British Heart Valve Society

For Education and Best Practice in Heart Valve Disease

BHVS Newsletter December 2020

British Heart Valve Society

For Education and Best Practice in Heart Valve Disease

Well well well…it's December 2020 and I have been in post for a year – and what an unusual year it has been. COVID-19 has turned the world on its head as we know it; still we are not out of the woods by any means, but the news of effective vaccines on the horizon has been understandably greeted with excitement and also relief. It is welcome for all to see - hopefully – some light at the end of what has been a long and dark tunnel this year.

One of the consequences of the viral pandemic has been the transition of medical conferences to online platforms – I am sure I am not the only one who has attended more online webinars and virtual conferences this year than all previous years in medicine added together! ESC, EACTS, BSE, TCT and – of course – our very own BHVS conference this year have all been held online as virtual meetings. There are without question some disadvantages, including the inability to meet old friends and acquaintances – yet the broad reach of such meetings is undeniable. As an example, the ESC congress this year attracted over 100,000 delegates (compared to ~30,000 usually).

In this bumper Christmas edition of the newsletter, we report on some major trials that were unveiled this year, including the 2 year results from the PARTNER 3 trial and also head-to-head trials in the TAVI world (SOLVE TAVI, SCOPE 1 & SCOPE 2). We also report upon some interesting papers published this year in the Journal watch, including the landmark RIVER trial that tested a novel oral anticoagulant – rivaroxaban – against warfarin in AF patients that have a bioprosthetic mitral valve replacement.

I am grateful to Dr Vishal Sharma and Professor John Chambers for their article on patient-prosthesis mismatch. I have added to this with a historical piece on the late Dr Shahbudin Rahimtoola, who passed away two years ago this month and was the first to coin the phrase and describe the concept of mismatch.

I am grateful also to Mamta Buch and Norman Briffa for their excellent contribution analysing a French study published earlier this year which gained a lot of headlines at the time – a study retrospectively comparing outcomes of valve-in-valve TAVI and re-do surgical aortic valve replacement in patients with failing bioprosthetic valves. In the absence of randomised trials, observational data are the only data we have – and randomised trials are essential!

There has been one change to our Council since the last newsletter – Dr Chris Allen has been elected as President of the British Junior Doctors Association (BJCA) and is thus replaced as BJCA representative on Council by London cardiology registrar Dr Nabila Laskar – welcome Nabila! Find out more about our newest Council member in the Meet a Council Member section on page 21.

The BHVS Annual Conference this year was replaced, as many of you will know, by two evening webinars we held last month. On November 12th we discussed mitral valve prolapse and on November 19th we held a symposium on tricuspid valve disease. The interest in these webinars was, pleasingly, truly fantastic! Over 700 people from 5 continents across the world registered for these webinars and they were very well attended, with delegates joining us from North and central America, the UK, mainland Europe and Asia. Read more about the conference on page 19.

Finally, all that remains is for me to wish you all a Merry Christmas and a Happy New Year! Stay safe in the festive period! As always, if there's anything you feel strongly about or would like to discuss, please do get in touch! do feel free to e-mail me at: *president@bhvs.org.uk*

Dr Benoy N Shah
President
British Heart Valve Society

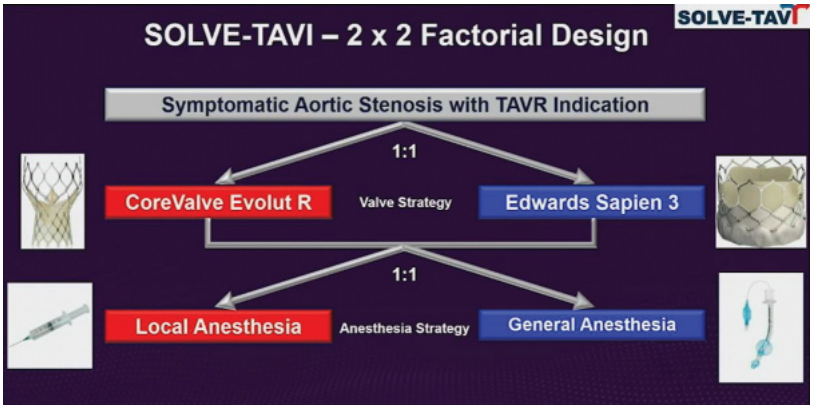
Congress News Roundup

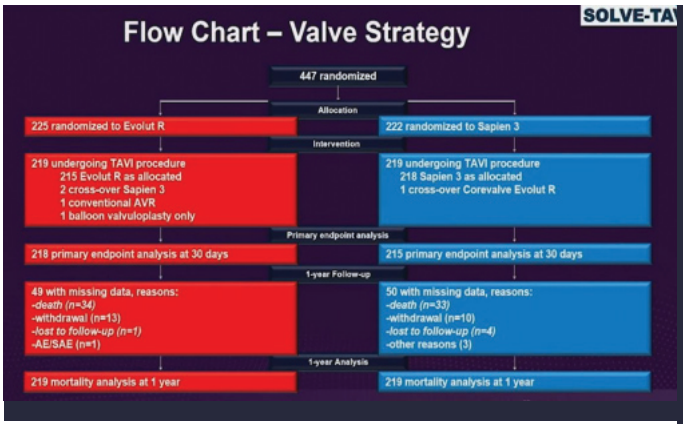
Dr Benoy N Shah

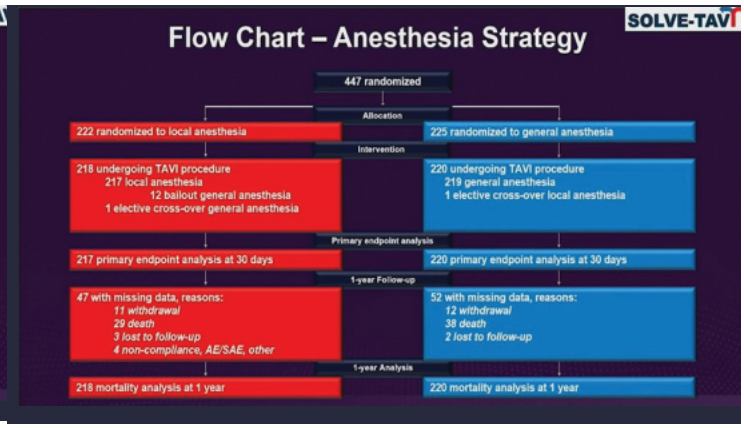
TCT 2020 – THE SOLVE TAVI Trial

The two most widely used transcatheter aortic valves around the world – the Edwards Sapien balloon-expandable (BE) valve and the Medtronic self-expanding (SE) CoreValve – have amassed a large body of evidence, when compared to surgical aortic valve replacement. There are certain technical and anatomical considerations that may make one select a BE or SE valve, but many patients being considered for TAVI may be suitable for either valve type and, until now, they had not been directly compared in a head-to-head trial. The SOLVE-TAVI randomized controlled trial set out to address this issue; the 30-day outcomes had already previously been published but, at the Transcatheter Therapeutics (TCT) 2020 virtual meeting, the 1-year data were presented.

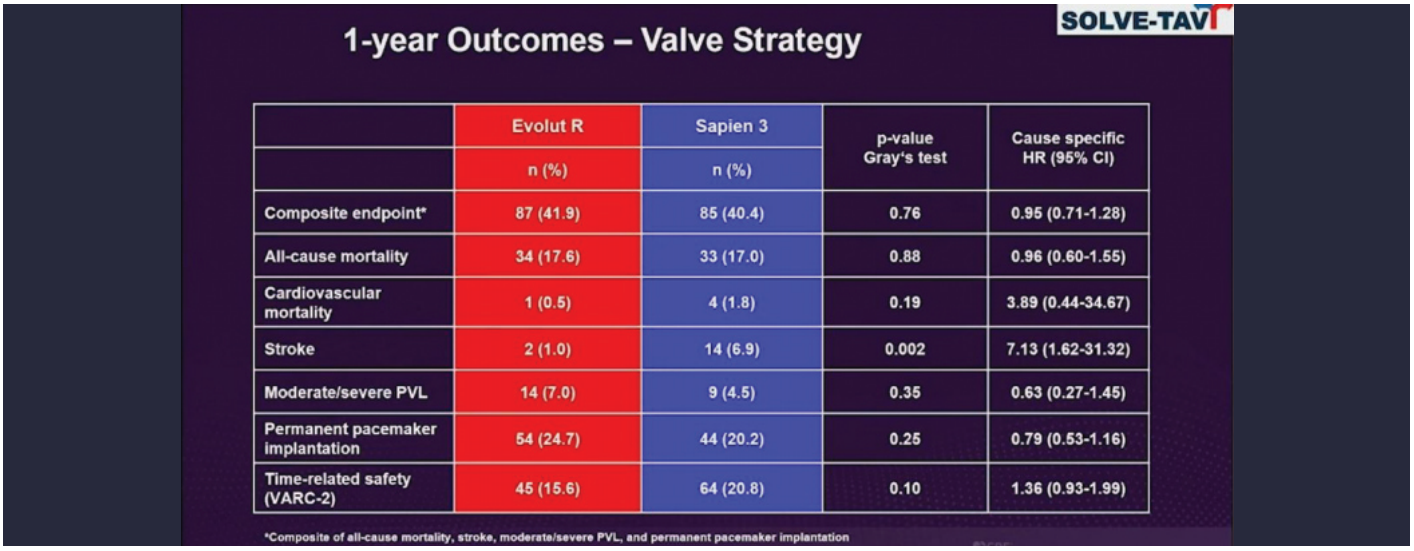
SOLVE-TAVI was a German 2 x 2 factorial randomized controlled trial in which patients were randomized to either a BE or SE TAVI valve and then also to either general (GA) or local (LA) anaesthesia. In total, 219 patients underwent TAVI in each arm (SE or BE and GA or LA). The original 30-day composite endpoint of the trial included all-cause mortality, stroke, moderate or severe paravalvular leak or need for permanent pacemaker insertion. The patient cohort was of intermediate-high surgical risk, with a mean age of ~81yrs, STS risk score of 7.6-7.7% and logistic Euroscore II of 5-6%. Atrial fibrillation was very prevalent in this population, with between 42-47% patients in AF.







At 1 year, there were no significant differences in primary outcomes except for stroke, which was significantly more common in the BE group than the SE group (6.9% vs. 1%, p = 0.002). There were no significant differences in outcomes between the GA and LA cohorts either. Peak and mean aortic valve gradients were significantly lower in the SE group than the BE group. The authors concluded that there were no significant differences in the total composite outcome between SE and BE valves and between GA and LA anaesthesia strategies, but SE valves were associated with a lower risk of stroke and better haemodynamics as assessed by echocardiography.



DISCUSSION

Although this trial was called the SOLVE-TAVI trial, unfortunately this trial has not really solved anything! We have just as many questions now as we did before this trial was conducted. Firstly, the trial was significantly underpowered to detect true differences between the groups in individual endpoints. This trial needed thousands rather than hundreds of patients. A multi-country, multi-centre RCT was needed in this instance. The performing TAVI centres were more familiar with the Medtronic SE CoreValve than the BE Sapien 3 system and this was evident from the outcomes – firstly, the permanent pacemaker rate of 20% in the Sapien group was far higher than that reported in previous studies with this valve. Of greater concern, however, was the 6.9% rate of stroke in this cohort – this was essentially a 7-fold increased risk of stroke compared to the SE TAVI group. No other trial of the Sapien TAVI system has produced a stroke rate this high before. The admission from the presenting physician that the German hospital teams were much more familiar with one device than the other also highlights one of the challenges of such trials, as ideally such trials need to be performed in high-volume centres that have equal expertise in both valves being tested. This may exclude many centres, however, as often a TAVI centre has a 'main' or 'default' valve with which they have more experience than other valves.

The trial has also not put to bed questions regarding whether a GA or LA anaesthetic strategy is best. The safety of these was compared in this trial although more meaningful outcomes may have included cost, need for ICU and length of hospital stay (these data may emerge when the final paper is published).

In summary, the SOLVE TAVI trial was a non-Industry funded head-to-head comparison of the two most widely used TAVI valves. No significant differences were observed at 1 year between the groups in mortality or myocardial infarction, although the BE Sapien 3 group had a considerably higher rate of stroke and both groups had high rates of permanent pacemaker implantation. Expertise within the performing centres may help explain some of these data that appear discrepant with prior studies.

TCT 2020 – The SCOPE Trials

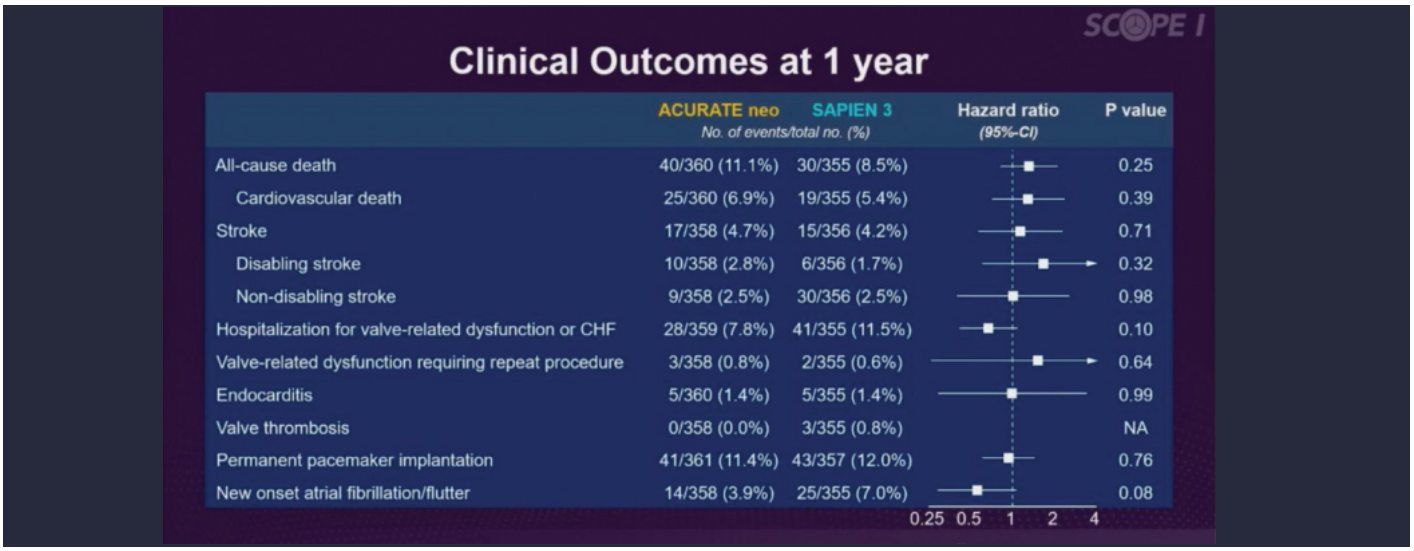
At the Transcatheter Therapeutics (TCT) virtual meeting in October, 1 year results were presented from two trials comparing Boston Scientific's self-expanding first generation Accurate Neo valve against the Edwards Sapien 3 balloon-expandable valve (SCOPE I trial) and the Medtronic self-expanding CoreValve (SCOPE II trials). In both trials, the Accurate Neo failed to meet the pre-determined statistical parameters for non-inferiority. Below we take a closer look at each trial in detail.

SCOPE I – Accurate Neo vs Sapien 3

Over a two year period (Feb 2017 – Feb 2019), 739 patients with symptomatic severe aortic stenosis were randomized across 20 centres in Europe to transfemoral TAVI with the Boston Acurate Neo (n = 372) or the Edwards Sapien 3 valve (n = 367). The primary endpoint was a combination of VARC-2 safety and clinical efficacy criteria at 30 days. This was therefore a large and complex composite endpoint that included all-cause mortality, stroke, life-threatening / disabling bleeding, major vascular complications, coronary artery obstruction requiring intervention, acute kidney injury stage 2 or 3, valve-related dysfunction requiring repeat procedure, rehospitalization for valve-related symptoms or heart failure, moderate-severe prosthetic valve regurgitation or prosthetic valve stenosis at 30 days.

Last year, the first results were presented at the TCT 2019 meeting with simultaneous publication in The Lancet. The mean age of the patients was 83yrs and mean STS-PROM score was 3.4-3.7%. The composite primary endpoint occurred in 23.7% of patients treated with the Acurate Neo and in 16.5% of Sapien 3-treated patients – this >7% difference meant the trial did not meet the agreed statistical criteria for noninferiority. In fact, Sapien 3 emerged as superior to the investigational device.

This year, at TCT 2020, the 1-year follow-up data were presented. In summary, there were no significant differences between the outcomes at 1 year. The rate of death / stroke was 12.5% (Accurate Neo) vs 9.2% (Sapien 3). The table below shows the major outcomes at 1 year, with no new significant differences between the groups, with one trend towards more atrial arrhythmia noted in the Sapien 3 group. The rate of paravalvular leak remained different between the two groups – in the Accurate Neo cohort, nearly 9% of patients had moderate or severe AR at 1 year compared with 3.6% in the Sapien 3 group (p 0.006). The Accurate Neo valve, being a self-expanding system, was associated with lower transvalvular mean gradients (11mmHg vs 7mmHg) and higher effective orifice areas (1.76 vs 1.50 cm2). The conclusion of this trial was that Accurate Neo did not meet non-inferiority when compared to Sapien 3 and, in fact, superiority analyses confirmed Accurate Neo as inferior to Sapien 3 in this trial.



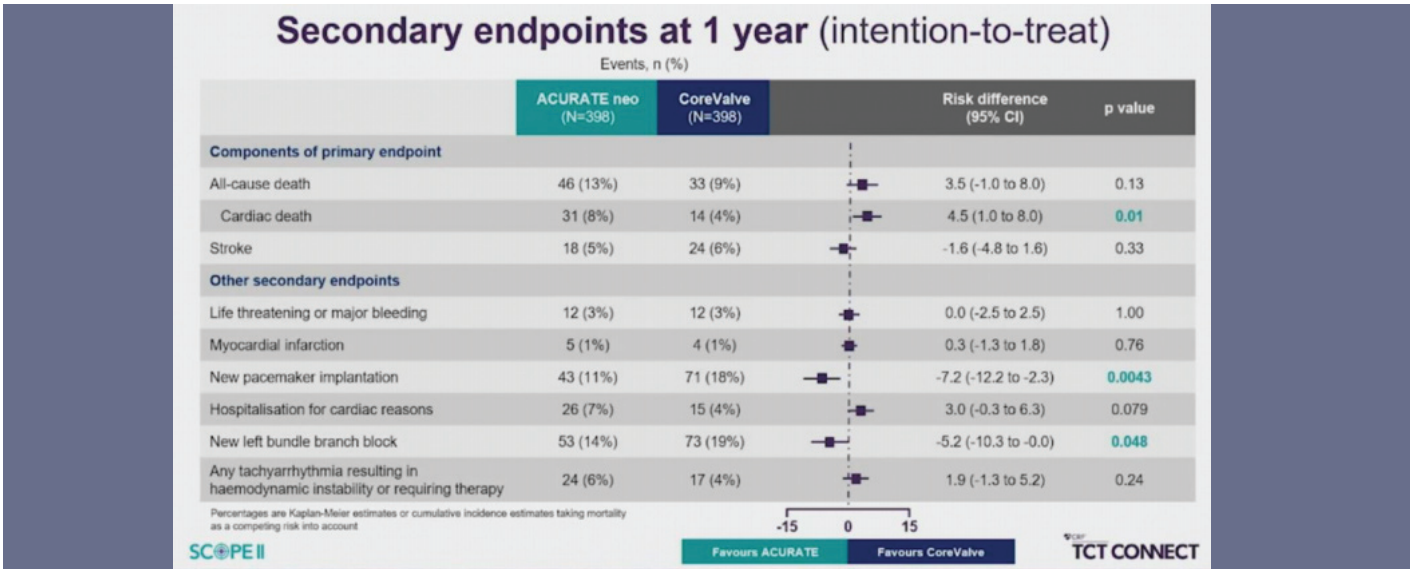
SCOPE 2 – Accurate Neo vs CoreValve

SCOPE 2 was also a randomized noninferiority study conducted at 23 European hospitals. The study included 796 patients aged ≥75 years (mean 83.2 years; 68% women) with symptomatic severe aortic stenosis. The mean STS-PROM score in this trial was 4.6%, suggesting an intermediate surgical risk population.

The researchers pre-specified they would perform both intention-to-treat and per-protocol analyses. The protocol stated that the Accurate Neo system would need to attain statistical non-inferiority in both analyses for this to fulfil the requirements for non-inferiority. In the end, the Accurate Neo system met the non-inferiority parameters

when compared to CoreValve with respect to the primary endpoint of death and stroke at 1 year (15.3% with Acurate neo vs 14.3% with CoreValve Evolut; P = 0.03 for noninferiority) in the per-protocol analysis but this was not true in the intention-to-treat analyses, thus, the authors could not claim non-inferiority.

At 30 days, there was a significantly increased risk of cardiac death among patients treated with Acurate Neo (3.0% vs 1.0% with CoreValve Evolut; P = 0.03), and this higher risk of cardiac death was still evident at 1 year (8.0% vs 4.0% with CoreValve Evolut; P = 0.01). As individual endpoints, there was no difference in the risk of all-cause mortality or stroke at 30 days or 1 year. The Acurate Neo device associated with significantly lower pacemaker implantation rates at 30 days (11% vs 18.0% with CoreValve Evolut; P = 0.0027). As in SCOPE I, there were higher rates of paravalvular leak with the Accurate Neo valve compared to the other valve (in this case, CoreValve Evolut R).



In conclusion, TAVI with the Accurate Neo valve did not meet non-inferiority criteria when compared to the CoreValve with respect to a composite of all-cause death and stroke at 1 year. In secondary analyses, the rate of cardiac death was increased amongst patients that received the Accurate Neo valve. The two bioprostheses differed with respect to rates of aortic regurgitation and new pacemaker implantation.

What next for the Acurate Neo?

There can be little doubt that these trials represent a significant setback for Boston Scientific, which would have been hoping to seek FDA approval for the Accurate Neo valve had non-inferiority been confirmed. As it is, in both trials non-inferiority was not shown – indeed, the Sapien 3 valve was superior to the Accurate Neo in SCOPE I and there was increased cardiac death in Accurate Neo patients in SCOPE 2.

A 2nd generation device, the Accurate Neo2, has already been launched in Europe, having received CE mark approval earlier this year. It has enhanced annular sealing technology and it is hoped this will reduce rates if paravalvular leak, a problem for the valve in both the SCOPE I and SCOPE 2 trials. The Accurate neo2 is being evaluated at present in the Accurate IDE (Investigational Device Exemption) trial, which is due to complete enrolment this year. It is planned that up to 500 patients will be randomized to the Accurate neo2, Sapien 3 or CoreValve Evolut R TAVI systems. The large composite primary outcome includes rates of all-cause mortality, stroke, life-threatening and major bleeding, stage 2 and 3 acute kidney injury and major vascular complications at 30 days.

Since these trials were presented at TCT, however, Boston Scientific has taken the interventional cardiology community by surprise by deciding to abandon altogether its other TAVI valve, the Lotus valve. Last month, Boston announced the immediate recall of all unused Lotus TAVI valves and immediate discontinuation of the Lotus program. Mike Mahoney, Boston Scientific chairman and chief executive officer, said "While we have been pleased with the benefits the Lotus Edge valve has provided to patients, we have been increasingly challenged by the

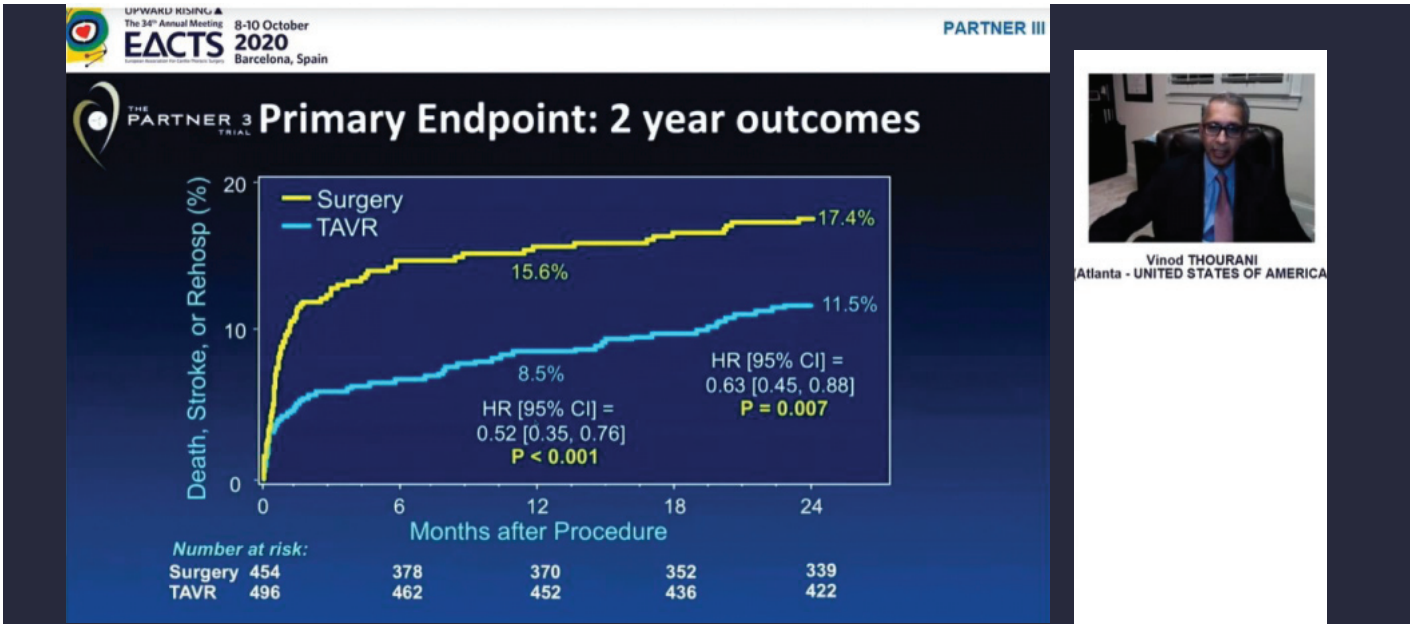
intricacies of the delivery system required to allow physicians to fully reposition and recapture the valve," "The complexity of the delivery system, manufacturing challenges, the continued need for further technical enhancements, and current market adoption rates led us to the difficult decision to stop investing in the Lotus Edge platform."

Boston stated that it wished to concentrate its efforts and resources on the Accurate Neo valve – thus placing an even greater importance on the Accurate Neo proving more successful than the 1st generation Neo valve. Time will tell if this gamble pays off for Boston!

EACTS 2020 – PARTNER 3 TRIAL – 2year update

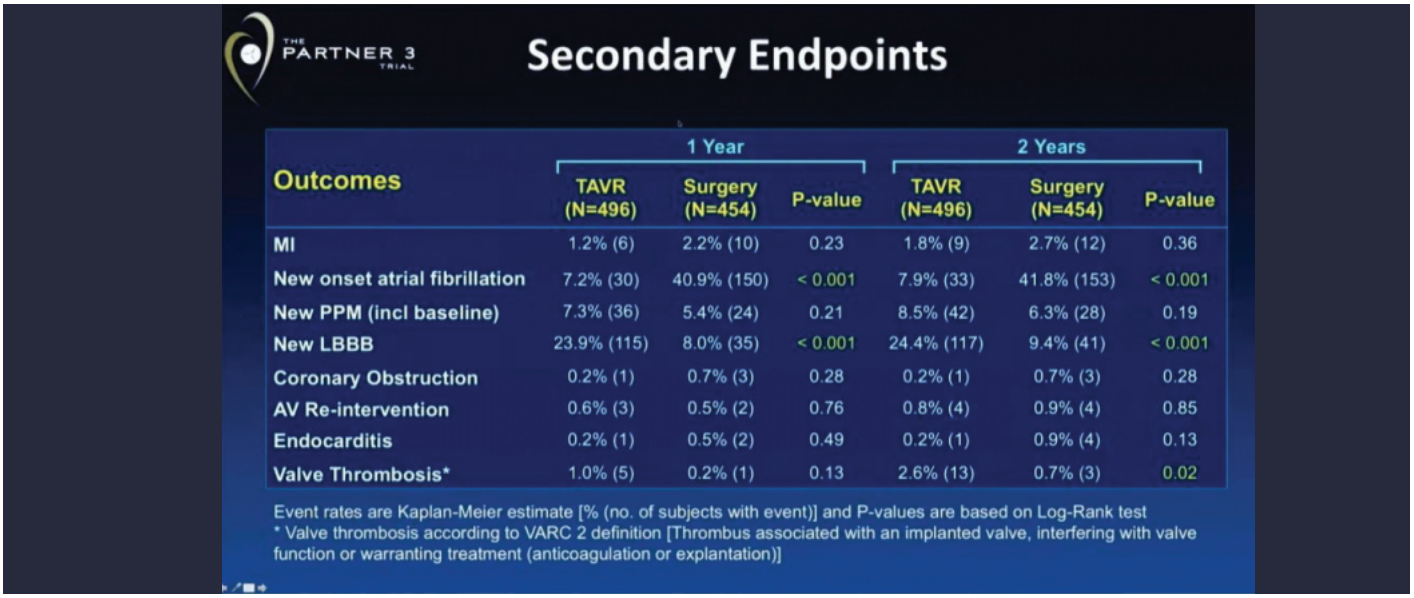
I was fortunate to be invited this year to be a "social media ambassador" for the EACTS 2020 annual congress! This was something I had not even heard of before, but it granted me free access to this excellent congress, so I didn't complain! This was a great meeting with a really impressive online virtual platform. One could "walk" around the virtual conference centre, see other delegates around you and walk into sessions to view the talks – very imaginative planning. There were many great sessions, but here I will summarise the 2year results of the PARTNER 3 trial presented at this meeting.

PARTNER 3, you will recall, was Edwards Lifescience's Phase 3 randomised trial of the Sapien 3 TAVI valve versus surgical valve replacement in low-risk patients. The 1-year outcomes had been unveiled to much fanfare at ACC Scientific Sessions 2019, after they showed that the Sapien 3 system was non-inferior to surgery and, indeed, in superiority statistical analyses, it emerged superior to surgery. However, these were 12month outcomes only. At EACTS 2020, Dr Vinod Thourani re-presented the 2-year outcomes.



Above: The overall primary end-point at 2 years still favoured TAVI over surgical AVR. However, this was driven by a difference in hospitalizations, since differences in death and stroke rates had disappeared by 24 months

There was still a statistically significant benefit for TAVI over surgical AVR at 2 years, although by this stage the difference between groups with regards to death (2.5% [TAVI] vs. 3.2% [AVR], p=0.47) and stroke (2.5% vs. 3.6%, p=0.28) were no longer significant, meaning that the significance of the composite endpoint was driven by lower hospitalizations in the TAVI cohort (8.6% vs. 12.5%, p=0.047). Furthermore, there were interesting data worth considering in the secondary outcomes.



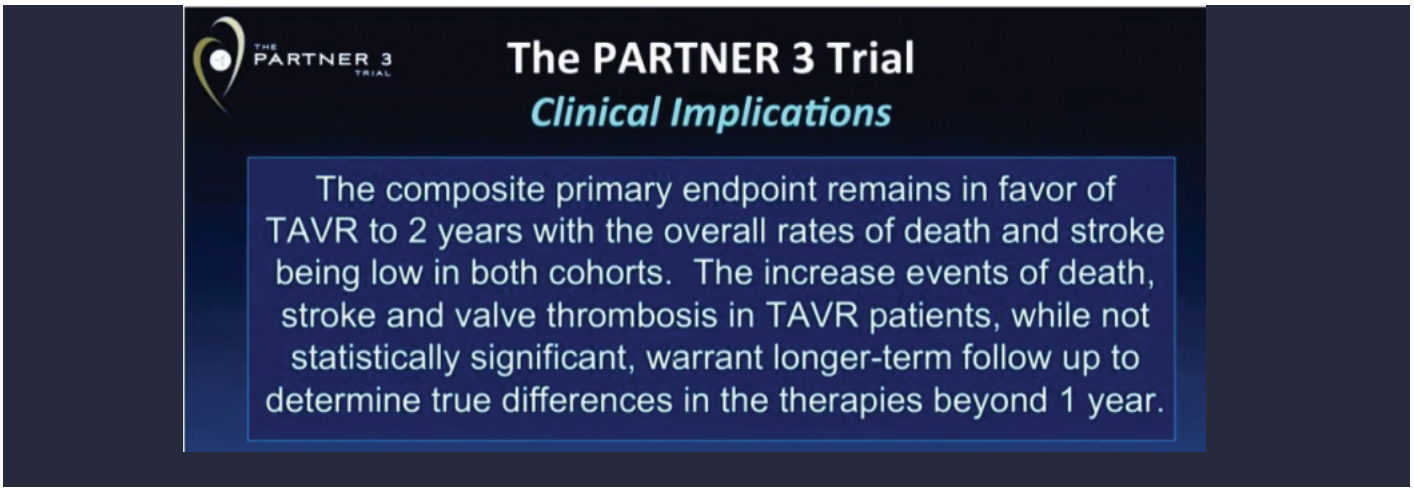
Outcomes	1 Year			2 Years		
	TAVR (N=496)	Surgery (N=454)	P-value	TAVR (N=496)	Surgery (N=454)	P-value
MI	1.2% (6)	2.2% (10)	0.23	1.8% (9)	2.7% (12)	0.36
New onset atrial fibrillation	7.2% (30)	40.9% (150)	< 0.001	7.9% (33)	41.8% (153)	< 0.001
New PPM (incl baseline)	7.3% (36)	5.4% (24)	0.21	8.5% (42)	6.3% (28)	0.19
New LBBB	23.9% (115)	8.0% (35)	< 0.001	24.4% (117)	9.4% (41)	< 0.001
Coronary Obstruction	0.2% (1)	0.7% (3)	0.28	0.2% (1)	0.7% (3)	0.28
AV Re-intervention	0.6% (3)	0.5% (2)	0.76	0.8% (4)	0.9% (4)	0.85
Endocarditis	0.2% (1)	0.5% (2)	0.49	0.2% (1)	0.9% (4)	0.13
Valve Thrombosis*	1.0% (5)	0.2% (1)	0.13	2.6% (13)	0.7% (3)	0.02

Event rates are Kaplan-Meier estimate [% (no. of subjects with event)] and P-values are based on Log-Rank test
* Valve thrombosis according to VARC 2 definition [Thrombus associated with an implanted valve, interfering with valve function or warranting treatment (anticoagulation or explantation)]

Above: Important secondary outcomes from the 2-year PARTNER 3 trial data

As an example, new onset AF after surgery remained astonishingly high at 41.8% - I must say I don't see anywhere near this level of new AF after surgery in my practice, unless a brief episode of AF post-operatively that reverts to sinus rhythm is still counted in the 2-year data. New LBBB was seen in a quarter of all TAVI patients and importantly, valve thrombosis (as defined by the VARC-2 criteria) was significantly more common in TAVI than surgery (2.6% vs. 0.7%, p=0.02).

There was much discussion about these results, but essentially the conclusion was that the longer-term follow-up that is planned for these patients (5yr and 10yr data) will be vital, as there was an increased incidence of death, stroke and valve thrombosis between months 12-24 for the TAVI cohort which warrants closer attention in future follow-up.



Above: Concluding slide from the PARTNER 3 2-year data presentation

Journal Watch

Dr Spiros Zidros

Rivaroxaban in Patients with Atrial Fibrillation and a Bioprosthetic Mitral Valve - RIVER study

In this multi-centre study, 1009 patients with a bioprosthetic mitral valve and AF were randomised to warfarin (INR range 2.0-3.0) or rivaroxaban 20 mg OD. The follow up duration was 12 months. The results showed that rivaroxaban is non-inferior for the primary outcome – a composite of cardiovascular death, stroke and major bleeding. This trial may well lead to a change in practice, which has traditionally used warfarin in this setting.

Guimaraes et al., N Engl J Med 2020; 383:2117-2126, DOI: 10.1056/NEJMoa2029603

Impact of Arterial Blood Pressure on Ultrasound Hemodynamic Assessment of Aortic Valve Stenosis Severity

This is a single-centre prospective study that included 100 patients with at least moderately severe AS. Echocardiographic indices of AS were obtained at 3 different haemodynamic conditions: SBP< 120 mmHg, SBP 120-150 mmHg and SBP > 150 mmHg, with the use of isosorbide dinitrate or phenylephrine. High SBP was shown to underestimate the degree of AS when this is based on gradients and velocities and not when based on AVAi and DI. This trial highlights the importance of measuring BP at the time of an echo study.

Hayek et al., J Am Soc Echocardiography, 2020 Nov;33(11):1324-1333. DOI:10.1016/j.echo.2020.06.013

Prevalence and Outcomes of Concomitant Aortic Stenosis and Cardiac Amyloidosis

This multi-centre study recruited 407 patients that underwent TAVI for aortic stenosis. All patients had a blinded pre- TAVI DPD scan which was not taken into account in the decision-making process. DPD was positive in 11.8% of the study cohort. Most of the cohort had TAVI (81.6%), 2.5% surgical AVR and the rest medical management. The results showed that aortic stenosis associated with cardiac amyloidosis had similar survival post TAVI compared to lone AS and TAVI did improve survival on these patients. These results were used by the authors to argue that amyloidosis in this cohort should not deny patients TAVI.

Nitsche et al., J Am Coll Cardiol. Nov 08, 2020, DOI: 10.1016/j.jacc.2020.11.006

Association of Bioprosthetic Aortic Valve Leaflet Calcification on Hemodynamic and Clinical Outcomes

This prospective study enrolled 204 patients 7 years after a surgical aortic valve replacement. At baseline, all patients had a non-contrast CT scan and an echocardiogram. At 3 years, 137 of the patients had echocardiographic follow up. As observed on the native aortic valves, valve calcification using AV calcium density (AVCd) is a strong predictor of valve deterioration, death and re-intervention, though there was no difference in the AVCd cut off between men and women.

Zhang et al., J Am Coll Cardiol. 2020 Oct, 76 (15) 1737–1748, DOI: 10.1016/j.jacc.2020.08.034

Brain Injury After Transcatheter Replacement of Bicuspid Versus Tricuspid Aortic Valves

This study was based on the TORCH registry (Transcatheter Aortic Valve Replacement Single Center Registry in Chinese Population). 204 patients that underwent TAVI were enrolled and 40.7% of them had Bicuspid aortic valve (BAV). The median age of the BAV patients and the Society of Thoracic Surgeons scores were lower. The results showed that the stroke risks were similar (higher in the BAV group but not statistically significant). BAV patients would have more brain lesions post TAVI and with greater volume.

Fan et al., J Am Coll Cardiol. 2020 Nov, 76 (22) 2579–2590, DOI: 10.1016/j.jacc.2020.09.605

Patient / prosthesis mismatch

Dr Vishal Sharma & Professor John Chambers

It is common to find a high velocity across a replacement heart valve in the aortic position. This can be caused by pathological obstruction or patient-prosthesis mismatch. Patient-prosthesis mismatch (PPM) means that the valve orifice area is too small for the size of the patient. All replacement valves have a smaller area available for flow than a normal native valve because of the presence of the stents or sewing ring and reduced compliance of the leaflets. However, below an EOAi 0.85cm2/m2 the transaortic velocities at rest rise exponentially and this is taken as the cut-point for moderate PPM. Severe PPM is taken as an EOAi less than 0.65cm2/m2 which is accompanied by higher event rates perioperatively and in the longer-term [1,2]. Lower cut-point values should be used in obese patients (body mass index ≥ 30 kg/m2) [3]. Partition values for mild, moderate and severe PPM for the aortic and mitral positions are shown in Table 1.

Table 1: Thresholds for patient-prosthesis mismatch in replacement aortic and mitral valves. [3]

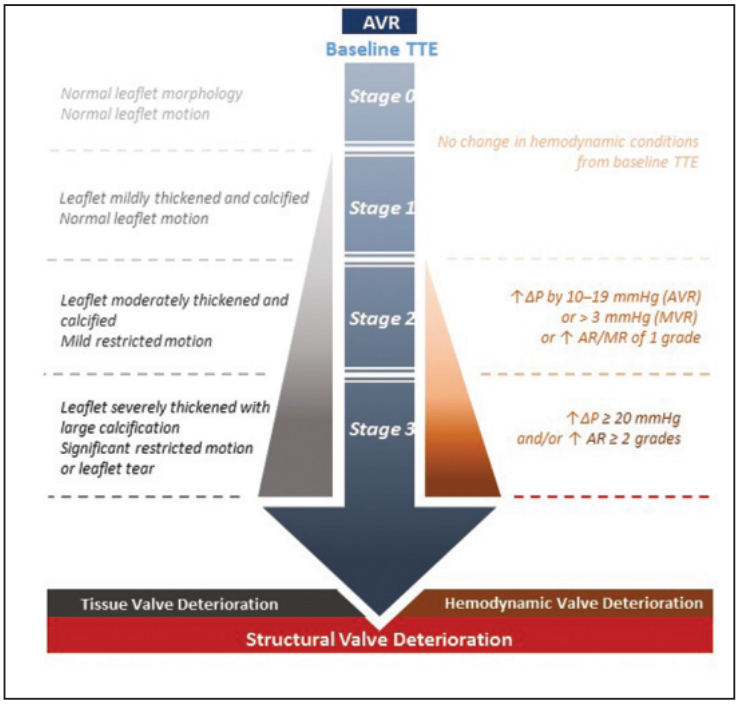
	Mild*	Moderate	Severe
Aortic (cm^2/m^2)	>0.85 (>0.70)†	0.65-0.85 (0.6-0.70)†	<0.65 (<0.6)†
Mitral (cm^2/m^2)	>1.2 (>1.0) †	0.9-1.2 (0.8-1.0)†	≤0.9 (≤0.8)†

† Values between parentheses are for obese patients, i.e. body mass index ≥ 30 kg/m^2

By contrast structural valve deterioration (SVD) occurs as a result of limited durability leading to failure of the valve. It is therefore characterised by the development of abnormal morphology or movement of the leaflets with initially normal haemodynamic function. As it progresses it is associated with a change in haemodynamic function (Figure 1). A proposed definition of moderate SVD in aortic replacement valves is:

- Thickening of the leaflets and
- An increase in mean gradient by >10 mmHg from the baseline study or
- New or worsening transvalvular regurgitation

Figure 1:



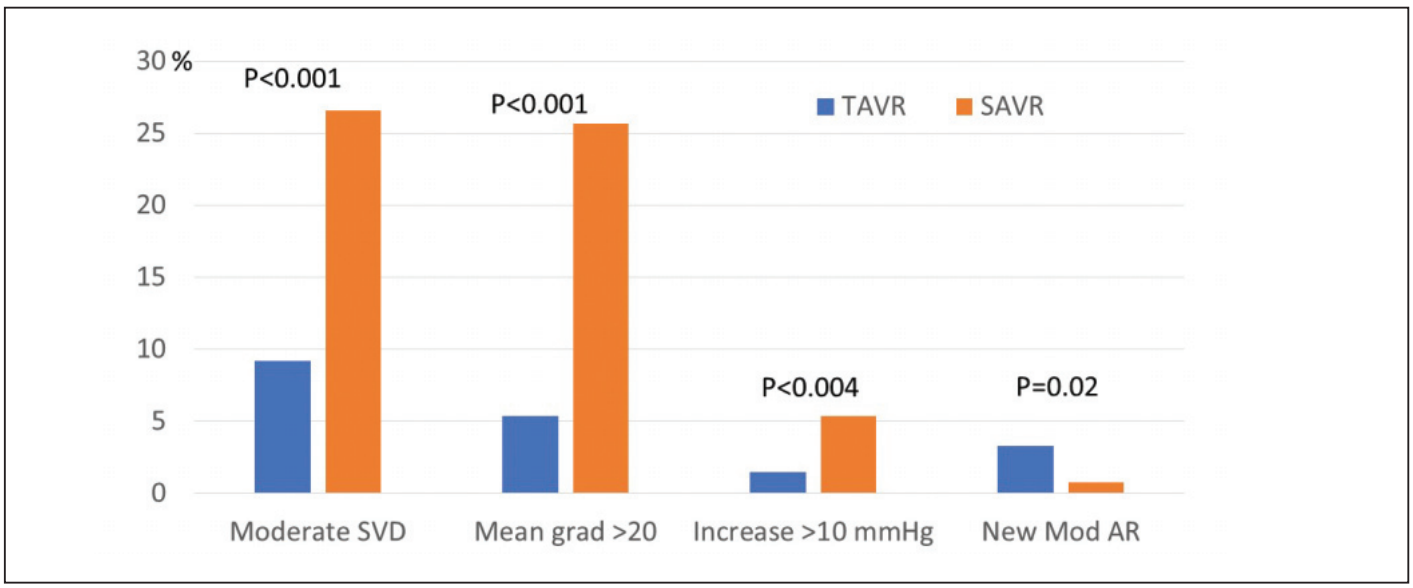
The key echocardiographic features suggesting PPM versus a pathological problem with the valve are shown in Table 2. Comparison with the early post-operative baseline echocardiogram is essential. Patients with PPM will usually have high velocities from the outset while a significant increase in velocity suggests valve dysfunction.

Table 2: Features to distinguish Patient-Prosthesis mismatch from valve dysfunction (for patients with reduced EOAi)

Finding	Favours PPM	Favours valve dysfunction
Valve Velocity	Normal or mildly increased velocities. Finding present on initial post-operative echocardiogram and unchanged	New finding of high velocities or a significant increase in velocity compared to baseline echocardiogram
Leaflet Appearance	Thin leaflets with no calcification	Thickened and calcified leaflets
Leaflet mobility	Normal	Thickened and calcified leaflets
Transvalve regurgitation	None/minimal	Increasing from earlier studies

A statement released in 2017 by European Association of Percutaneous Cardiovascular Interventions [4] inappropriately allowed SVD to be defined solely by an absolute mean gradient ≥20 mmHg. In fact, a mean gradient of ≥20 mmHg is often found immediately after implantation and represents patient prosthesis mismatch and not SVD. This error has caused significant confusion leading to a perception that TAVI has good durability. Thus in recent studies [1,2] comparing TAVI with surgical valves, apparent failure rates were dominated by absolute mean gradients ≥20 mmHg (Figure 2). However new transprosthetic regurgitation, a robust sign of SVD, was less common in surgical bioprostheses than TAVI.

Figure 2:



Severe patient prosthesis mismatch (PPM) should be avoided. The surgeon can do this in patients with smaller roots by choosing a replacement valve with as large an effective orifice area as reasonable. Sometimes the avoidance of PPM is a criterion for choosing a TAVI in place of a surgical replacement. It is vital to understand the difference between PPM and structural valve deterioration since this can cause important confusion in the comparison of durability between TAVI and surgical replacement valves.

References

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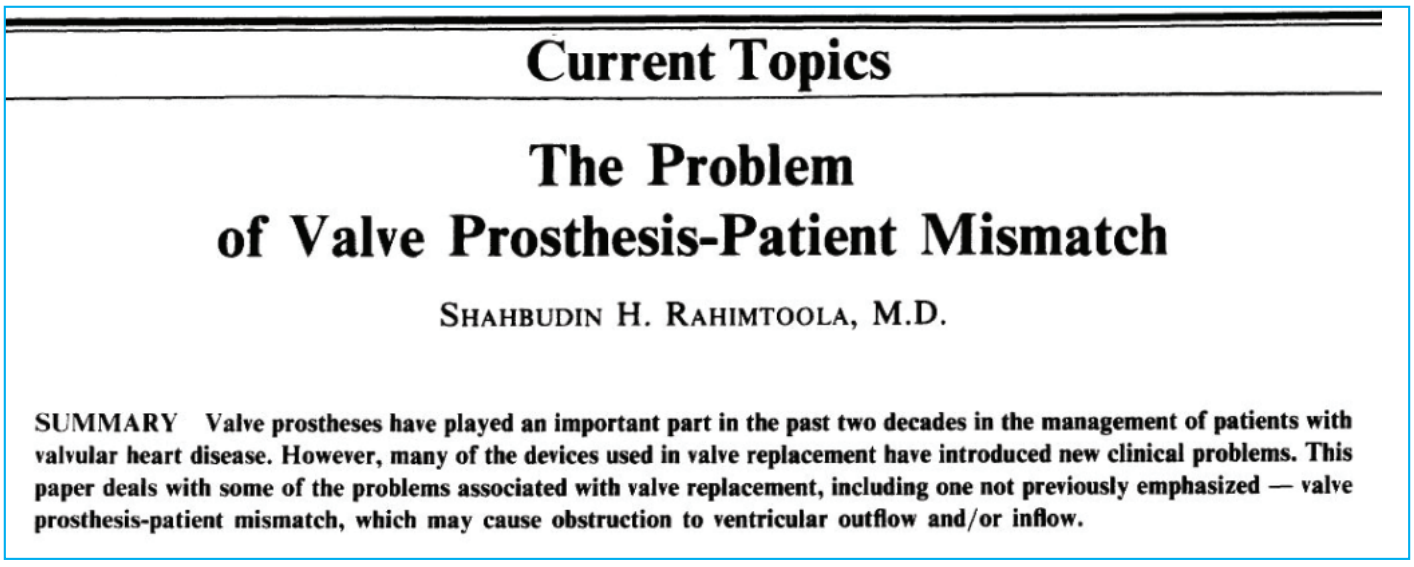
Heart Valve History - Patient / prosthesis mismatch and Shahbudin Rahimtoola

Dr Benoy Shah

In combination with the previous article on patient prosthesis mismatch, I thought it would be of interest to go back and explore the origin of this term and re-visit the life of the cardiologist that first described mismatch – the late Professor Shahbudin Rahimtoola.

Rahimtoola was born in Mumbai, India in October 1931. He came from an eminent family – his father, Hoosenally Rahimtoola, was the city's Mayor from 1935-35, as was his grandfather Jaffer Rahimtoola from 1909-1910. The nation's partition in 1947 prompted a move to the newly created Pakistan. He undertook medical studies at Dow Medical College in Karachi before moving to the UK for further training. In the 1950s he worked in the Royal Postgraduate Medical School in London.

He obtained Fellowship of the Royal College of Physicians of Edinburgh in 1963 but, later that year, moved to the Mayo Clinic in Rochester, USA working under Dr Jeremy Swan at an exciting time of enormous growth in cardiac catheterization, cardiopulmonary bypass and cardiac surgery. From Mayo Clinic, Rochester he moved to another high-profile institution – Cedars Sinai Hospital in Los Angeles before joining Cook County Hospital in Chicago as Chief of Cardiology in 1969. This was a brief stay in the Windy City, however, as he was recruited just 3 years later to become Chief of Cardiology at the University of Oregon. His academic output and collaborations were impressive, working on one of the first randomized controlled trials in coronary bypass surgery as well as natural history studies on conduction system disturbances. It was during his stint in Oregon – in 1978 [the year of the author's birth (!)] – that Rahimtoola published a paper in Circulation entitled "The problem of patient -prosthesis mismatch". In Oregon, he also worked alongside legendary cardiac surgeon Albert Starr (of Starr-Edwards valve fame).



Current Topics

The Problem of Valve Prosthesis-Patient Mismatch

SHAHBUDIN H. RAHIMTOOLA, M.D.

SUMMARY Valve prostheses have played an important part in the past two decades in the management of patients with valvular heart disease. However, many of the devices used in valve replacement have introduced new clinical problems. This paper deals with some of the problems associated with valve replacement, including one not previously emphasized — valve prosthesis-patient mismatch, which may cause obstruction to ventricular outflow and/or inflow.

Above: The original description of patient-prosthesis mismatch, published in Circulation in 1978

In 1980, Rahimtoola moved again when he was appointed Professor and Chief of Cardiology in the University of Southern California. It was in this post that Rahimtoola popularized the phrase 'hibernating myocardium' to refer to dysfunctional but viable myocardium, in which he had noted that myocardial segments presumed infarcted improved contractility after revascularization. Rahimtoola retired as Distinguished Professor of Cardiology in 2018. He died, aged 87, on December 9th 2018. Rahimtoola was previously cited by former ESC President Roberto

Ferrari as one of the greatest influences in his career. In the days and months following his death, eminent cardiologists such as former ESC Presidents Roberto Ferrari and Jeroen Bax paid tribute to an individual they remembered as kind, intelligent and compassionate.

Rahimtoola was awarded the European Society of Cardiology's Gold Medal in 2009 and the American College of Cardiology's Lifetime Achievement Award in 2013 for contributions to cardiovascular medicine.

I had the pleasure of meeting Prof Rahimtoola at the ESC Congress 2011 in Paris, where we had a brief conversation about his time in England. I was also pleasantly surprised when he replied to an e-mail I sent him about a patient I was looking after a few years ago! The patient in question had been of normal body mass index (BMI) when they had undergone aortic valve replacement.

However, in the years since surgery significant weight gain had resulted in a low indexed aortic valve area and exertional breathlessness. I contacted SR to enquire if it was possible for an individual to 'acquire' or develop PPM years after initial operation, for example due to weight gain. He replied at length explaining one could indeed observe such a phenomenon. The e-mail exchange is included below:

Above:
With Prof Rahimtoola at the ESC Congress in Paris (Aug 2011)
Well, he asked me for a photo; I couldn't say no!

From: Shah, Benoy
Sent: Friday, July 10, 2015 2:49 AM
To: Shahbudin H Rahimtoola
Subject: Patient Prosthesis Mismatch - A question from Wessex, UK

Dear Dr Rahimtoola

My name is Benoy Shah, I am a cardiologist in Southampton, England. I hope you don't mind me contacting you, but I have a question about PPM that I have been unable to find an answer to in textbooks or papers on the subject.

The question I have is: Can PPM develop late after valve replacement (i.e., if a patient gains weight over time) or is PPM only a condition that is present from the time of implantation? That is, maybe at time of insertion the prosthesis size was appropriate, but if a patient gains a lot of weight over time and the BSA increases, then maybe they might "develop" PPM later on?

The reason I ask is that I have a patient with a Carbomedics AVR and high gradients (peak gradient 80mmHg). The indexed EOA now is 0.7 and fluoroscopy shows normal motion of both occluders. She thinks she has gained at least 2 stones in weight over these 20years since AVR, so I am wondering if she now has 'developed' PPM?

Thank you very much in advance.

Benoy

Dr Benoy Shah
Consultant Cardiologist
Wessex Cardiothoracic Centre
Southampton, UK

From: Shahabudin H Rahimtoola
Sent: 10 July 2015 19:52
To: Shah, Benoy
Subject: REPLY- Re: Patient Prosthesis Mismatch - A question from Wessex, UK

Dear Dr. Benoy Shah:

Thank you for writing to me. Please see my original description of this syndrome (Rahimtoola SH Circulation 1978;58:20-4) and a recent extensive review (Daneshvar S, Rahimtoola SH JACC 2012;60:1123-35).

All prosthetic heart valves (PHV) have an EOAi that is less than that of normal human valve and thus by definition all PHV have VP-PM. This includes the pulmonary autograft which narrows further over time, for example, at 5 years of follow-up.

Thus, your patient had, by definition, VP-PM at time of valve insertion. Since she has gained a lot of weight (28 lbs) the EOAi is worse now. The definition of mild VP-PM is EOAi > 0.9 cm2/m2, severe VP-PM is < 0.6 cm2/m2 and moderate VP-PM is > 0.6-0.9 cm2/m2. At the present time your patient has moderate VP-PM. There is no data that moderate VP-PM is associated with an increased mortality; moderate VP-PM is like moderate AS. Peak gradient by echo/Doppler is questionable to assess severity of aortic heart valve(s), both native and prosthetic (Rahimtoola JACC 2011;58:1197-1207).

I believe your patient should be a) Reassured; b) Should be strongly advised to lose weight; c) Should receive usual treatment (e.g. anti-coagulants) and appropriate other cardiac and non-cardiac therapy; and d) Advised that additional weight gain puts her at an increased risk of severe VP-PM which may be a serious problem.

Best regards,

Shahbudin H. Rahimtoola, MB, FRCP, DSc (Hon)

Valve-in-Valve TAVI vs Re-Do Surgery

Dr Mamta Buch & Professor Norman Briffa

The implantation of bioprosthetic aortic valves has greatly increased in recent years and this trend has extended to the <65 years population (1,2). The limited durability of these valves compared to mechanical prostheses in patients with a longer life expectancy presents a significant clinical challenge (3).

Redo sAVR is the guideline-directed mode of intervention for structural valve degeneration (4). It is, however, associated with higher morbidity and mortality compared to primary sAVR, attributable to technical aspects of surgery, age and co-morbidities. The rapid evolution of transcatheter aortic valve implantation (TAVI) has led to adoption of Valve-in-Valve (ViV) TAVI for a failing bioprosthesis as an appealing alternative to redo-sAVR and has already become the preferred option in patients who are considered at higher surgical risk (5,6).

There are limited comparative data for ViV-TAVI to redo-SAVR and, so far, no randomised controlled trials. The 3-year follow-up data of the PARTNER II - Nested Registry 3/Valve-in-Valve study showed that TAVI for prosthetic aortic valve degeneration was associated with favourable survival, sustained improved valve haemodynamics and quality-of-life outcomes. A recent study by Deharo et al published in the Journal of American College of Cardiology (7) adds to the retrospective evidence base and utilised the French administrative hospital-discharge database to compare ViV TAVI to redo-sAVR for treatment of aortic bioprosthetic failure between 2010 and 2019.

This was a propensity score-matched study in which, out of a total of 4327 patients in the database, the outcomes of 717 patients were analysed in each arm. Patients who underwent ViV TAVI were older and had higher co-morbidities compared to patients treated with redo sAVR. There was also a trend over time with more ViV TAVI cases in recent years, reflecting the wider, worldwide clinical adoption of ViV TAVI.

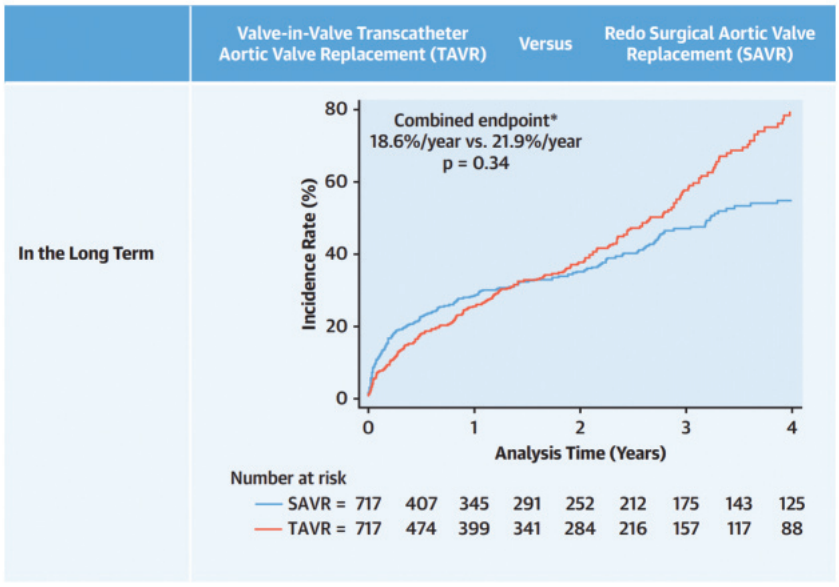
The key findings reported were:

- ViV TAVI was associated with lower rates of 30-day primary outcome, a composite of mortality, stroke, myocardial infarction, major or life-threatening bleeding, compared with redo SAVR for failed aortic bioprosthesis (odds ratio [OR], 0.62; 95% CI, 0.44-0.88; P= .03).
- Atrial fibrillation rates were lower in ViV TAVI whilst permanent pacemaker rates were lower in redo sAVR patients.
- Rehospitalisation for heart failure were more frequently reported in the ViV TAVI group and cardiovascular death rates were higher during follow up in the lower risk (EuroSCORE II <5%) ViV patients.
- During a median follow up of 516 days, the combined endpoint of cardiovascular death, all-cause stroke, myocardial infarction, or rehospitalisation for heart failure was not different between the two groups (OR, 1.18; 95% CI, 0.99-1.41; P= .26).
- A crossing of the composite outcome survival curves during follow-up (see Central Illustration) was observed resulting in a markedly lower cumulative event rate for redo sAVR 4 years post-intervention
- A time dependent interaction between all-cause and cardiovascular death was observed for the periods 2010-2015 and 2016-2019 with lower rates of all-cause death and significantly lower cardiovascular death with ViV TAVI compared to redo-sAVR in the 2016-2019 period.

This study is a useful comparative study of ViV TAVI and re-do sAVR for bioprosthetic aortic valve degeneration. It does, however, have significant methodological limitations inherent to its retrospective nature of a heterogeneous patient population and its reliance on administrative data which were not systematically checked and for which data completeness is unknown. Inclusion was also limited to patients with a primary diagnosis of aortic stenosis due to lack of reimbursement for aortic regurgitation in France.

The lower 30-day outcomes in the ViV TAVI group are consistent with previous retrospective studies which have described early benefit with respect to in-hospital adverse outcomes and length of hospital stay (7-9). The CI for all cause stroke and myocardial infarction in the ViV TAVI group in this study are, however, large which is not readily explained. The signal of a survival advantage is seen in previous studies with mean follow up periods of

CENTRAL ILLUSTRATION Incidence of the Combined Endpoint in Long-Term Follow-Up



Deharo, P. et al. J Am Coll Cardiol. 2020;76(5):489-99.

*Combined endpoint: cardiovascular death, all-cause stroke, myocardial infarction, and rehospitalization for heart failure.

up to 18 months (7,10). It is not possible in this study to drill down further to explain this finding due to lack of detail such as original size of bioprosthetic valve and post-procedural echocardiography data, lack of information on left ventricular function or previous bypass grafts or extent of coronary disease.

Possible reasons for increased longer-term mortality for ViV TAVI patients include patient-prosthesis mismatch (PPM) and moderate or greater paravalvular leak (PVL). PPM is a known predictor of mortality post-sAVR (11) and moderate or greater transvalvular gradients have been observed in approximately 60% of ViV TAVI patients (12). Higher rates of both PPM and PVL in ViV TAVI have been observed in meta-analyses when compared to redo sAVR (10,13). Higher rates of pacemaker implantation as well as underlying aetiology of native valve disease (bicuspid or degenerative) are also important factors to consider.

Surgical data vary widely with inadequate long-term systematically collected core-laboratory data but surgical series suggest that long-term outcomes for redo sAVR remain relatively stable up to 10 years post-operatively (14). Relatively little data are available for ViV TAVI beyond 3 years. The impact of early valve thrombosis is also not fully understood (15).

Overall, the findings of this study might be considered as reflective of experience with surgical therapy in other cardiovascular conditions, and the associated higher upfront adverse events but improved longer-term outcomes. There is the need for longer comparative follow up data that reflects contemporary practice and a well-designed randomised controlled trial would help to clarify relative merits of redo sAVR and ViV TAVI. Newer technology may be expected to continue to develop to improve bioprosthetic valve durability as well as preparing for future re-intervention.

This study is both a confirmation of the remarkable advances that TAVI and ViV TAVI have brought to our patients, with marked reduction in invasiveness and the rapid return to normal activities of daily living compared to redo sAVR, and a reminder that our enthusiasm should be tempered with caution. Heart team-based decision-making that integrates clinical, anatomical and technical factors in the context of individual patient quality of life and life expectancy remains central to supporting optimal outcomes for patients requiring re-intervention for aortic bioprosthesis degeneration.

Key learning points:

- Redo sAVR and ViV TAVI are evolving, complementary modes of intervention for degenerating surgical aortic bioprostheses.

- The trend to treat patients with a life expectancy >10 years with surgical bioprosthetic aortic valves should be very carefully considered due to higher rate of SVD
- The increased use of surgical bioprosthetic aortic valves requires increased surveillance for detection of SVD and timely re-intervention
- The clinical challenge presented by increased bioprosthetic sAVR requires heart valve team decision making to ensure prosthesis choice takes sight of life expectancy of the patient and of potential further intervention in the future
- ViV TAVI should be considered in patients with degenerating aortic valve bioprosthesis who have life expectancy <5 years, are above 80 years age and/or are considered inoperable or high surgical risk
- Standardised protocols to report long-term durability of surgical bioprosthetic aortic valves are required as this is an important benchmark for applying transcatheter techniques (16)

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BHVS Virtual Annual Conference 2020 (Webinars)

Dr Nabila Laskar & Dr Benoy N Shah

Many months ago, it became apparent that we would not be able to hold our Annual Conference, as planned, in the Holiday Inn in London. Early on, we contacted our speakers who had previously agreed to deliver talks and who very kindly offered to help with an online meeting. Our excellent and tireless Education Secretary, Dr Laura Dobson, put together two highly educational webinars which we held last month. Our former BJCA representative, Dr Chris Allen, recommended an AV company to us – ESW Solutions Ltd. This was a fantastic recommendation, as they handled the recording of the talks, live streaming of the event and Q&A session at the end with great skill and, most importantly, without any IT glitches!

Thursday Nov 12th – Mitral Valve Prolapse

Each webinar consisted of three talks, followed by a 30-minute panel discussion chaired by Benoy Shah. The mitral valve prolapse session was kicked off by Dr Madalina Garbi from Royal Papworth Hospital in Cambridge, speaking on "Mitral Valve Prolapse- What does the surgeon need to know?" Dr Garbi discussed the factors influencing surgery, the typical echocardiographic predictors of surgical success and the potential post-operative complications following mitral valve repair for MVP. For anyone that performs echocardiograms prior to surgery, this was a must-see talk! Next, we had a superb insight into the operating theatre with a talk on mitral valve repair surgery from Mr Ishtiaq Ahmed, consultant cardiac surgeon at Brighton and Sussex University Hospitals. Mr Ahmed highlighted the importance of a comprehensive assessment of mitral valve anatomy pre-operatively for MVP. He guided us through 3 cases from a 'surgeons view' illustrating the Neochord technique he commonly uses. Lastly he summarised Minimal Access Surgery including the pros and cons of adopting this method. His talk included several intra-operative clips which really helped to explain the repairs he was describing and was a helpful insight for cardiologists that rarely venture into theatre! Finally, Dr Bushra Rana – consultant cardiologist at Imperial Healthcare NHS Trust in London, gave a talk on the enigmatic Mitral Annulus Disjunction (MAD) Arrhythmic Syndrome. Dr Rana set the scene by reviewing the literature on MVP and ventricular arrhythmias and went on to describe the definition of MAD. She described the echocardiographic and anatomical features distinctive of MAD and concluded by discussing the management of these patients.

Mitral Valve Q&A session

Our panel were invited to answer some questions. Mr Ahmed confirmed that he does like all mitral valve patients to have had a TOE prior to surgery, usually including 3D assessment, to ensure that the valve anatomy is fully understood. All the panellists and the Chair were in agreement that MAD is a tricky diagnosis at present, as no specific treatment per se exists and more work is needed at this stage to understand the benefits of making a MAD diagnosis and management algorithms need to be developed. Other pertinent points to take way from this discussion were that surgical treatment of degenerative mitral valve disease should be an MDT discussion, the mitral valve gradient post repair should be interpreted with consideration of loading conditions and haemodynamics and Holter monitoring in patients suspected to have MAD is advised where the morphology of ventricular ectopics should be considered along with the frequency.

Thurs Nov 19th – Tricuspid Valve Disease

Our second webinar was dedicated to the tricuspid valve, often referred to as the forgotten valve or the 'Cinderella' of heart valve disease. However, in the transcatheter arena, there has been more activity in tricuspid devices & interventions than other areas of late, so an update felt pertinent.

The session was kicked off by Dr Jim Newton, consultant cardiologist in Oxford, who discussed the imaging aspects of tricuspid valve disease. Dr Newton provides peri-procedural imaging (2D & 3D TOE) for transcatheter tricuspid interventions in Oxford and went through his method of evaluating the tricuspid valve by TTE and TOE, including understanding which cusp is which in each view – not always easy on TOE! Dr Newton gave us an overview of the tricuspid valve anatomy and aetiologies of primary and secondary TR. He discussed the challenges in imaging the tricuspid valve along with the benefits of 3D imaging and utilizing other modalities to obtain information.

The next talk, entitled "The Tricuspid Valve – when to intervene and how", was delivered by Professor Rakesh Uppal, consultant cardiac surgeon at St Bartholomew's Hospital in London. Professor Uppal presented the literature of tricuspid valve interventions for TR. He discussed the current European guidelines and introduced us to the different techniques for tricuspid valve repair. It was clear to all listening that failure to address the tricuspid valve and dilated right ventricle at the time of mitral surgery, for example, often resulted in late severe TR and impaired outcomes due to heart failure.

The final talk, "Transcatheter Interventions in Tricuspid Regurgitation", was delivered by Dr Newton's colleague in Oxford, consultant cardiologist Dr Sam Dawkins. Dr Dawkins undertook structural heart interventional training in America for 2 years before returning to the UK. He discussed the challenges of transcatheter TV repair along with the challenges of imaging (complex anatomy, distance from TOE probe, shadowing). He summarised the evolution of devices historically used for TV repair and highlighted the TRILUMINATE study. He concluded with a case demonstrating the MitraClip being used to treat severe TR. Transcatheter tricuspid valve interventions are in their infancy, especially in the UK, but represent an exciting and promising field, especially for patients suffering with right heart failure due to severe TR that are not candidates for cardiac surgery.

Tricuspid Valve Q&A Discussion

The Q&A started with a discussion on how training in advanced structural techniques is limited in the country due to restricted numbers of cases. Dr Dawkins confirmed that a UK interventional trainee that wished to learn complex structural interventions (e.g. MitraClip, TriClip, paravalvular leak plugging etc) would almost certainly need to travel overseas for such experience, either to North America or certain European centres in Germany or Switzerland. There was a debate on how often TV repair was considered in accordance with European guidelines when MV surgery is performed. The session concluded with a discussion on pacemaker-related TR, the interventional approaches (transcatheter and surgical) to treatment and the role of intra-operative TOE in aiding these interventions.

Overall, these two webinars were a huge success – hundreds of delegates from around the world registered for these meetings and we hope you all enjoyed them! If you missed it, don't worry – all talks will be available to view in the Members Area section of the BHVS website within a few weeks.

Meet a council member!

Dr Nabila Laskar

In the *Meet a Council Member!* page, you can get to know a little more about the individuals working on behalf of the Society to educate, promote and inform on all matters related to heart valve disease. This edition, we focus on **Dr Nabila Laskar**, our BJCA representative on BHVS Council.

Personal and professional

Mrs Nabila Laskar

Born and raised in...
Watford, Hertfordshire

Place of work...
St Bartholomew's Hospital, London

Job Description ...
Cardiology registrar & Research Fellow

First Qualified in
2010

Role in work...
I am currently at the beginning of my MD (Res). I am looking at community detection of VHD and impaired LV function in a north east London, urban community, while also training primary care staff in hand-held echocardiography

Role in BHVS...
BJCA Representative

Interested in valve disease because…
Pathology of heart valve disease combines all aspects of cardiology and cardiac surgery enabling a true multidisciplinary team approach to patient management. I personally love how far multimodality imaging of heart valves has come.

Outside work

Favourite food?
It changes all the time…
but Thai stands the test of time!

Favourite restaurant?
CUT – 45 Park Lane, London

Favourite holiday destination?
Far East – Singapore, Malaysia, Thailand, Indonesia

Who do you most admire?
My inner circle of family & friends

Pet hate?
Lying

Favourite musician?
Mariah Carey

Favourite movie?
Pretty Woman

Star Wars or Star Trek?
Neither – I prefer Marvel!

Wine, beer or spirits?
None – and I don't like coffee or fizzy drinks either!

Superpower you would most like?
I would love to be Invisible – think of all the places you could be, people you could see, things you could do and no one would ever know!

Newsletter December 2020 – Contributors

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