Minimalism in TAVR

John Webb MD

Director interventional cardiology, St Paul's Hospital
McLeod Professor of heart valve intervention, University of British Columbia
Medical director transcatheter heart valve program, Province of BC
Vancouver, Canada

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

UBC

Consultant:

- Abbott
- Edwards Lifesciences
- Gore
- Medtronic
- Mitralign
- Orford
- St Jude Medical
- Transverse Medical
- Siemens
- Valtech
- Vivitro

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

Vancouver Coastal Health

Vancouver Transcatheter Heart Valve Program
St. Paul's Hospital
Office Number – 5CD
1081 Burrard Street
Vancouver BC, V6Z 1Y6
Tel : 604-806-XXXX
Fax : 604-806-9878

Patient Information:

Name: _____

DOB: _____ M F

PHN: _____

Address: _____

City: _____ Postal Code: _____

Telephone Number(s): _____

Alternate Contact(s): _____

REFERRAL FORM – Evaluation for transcatheter heart valve procedure

Date: _____ Number of pages (including this one): _____

Referring physician: _____ Contact #: _____

Family physician: _____ Contact #: _____

Current patient status: ☐ Elective

☐ In-patient – Hospital: _____ Unit: _____

VALVULAR HEART DISEASE TYPE:		
☐ Referral for transcatheter aortic valve implantation (TAVI)	☐ Aortic stenosis	☐ Aortic insufficiency
	☐ Native valve	☐ Previous aortic valve replacement (valve-in-valve referral)
Comments:		
☐ Referral for transcatheter mitral valve procedure	☐ Mitral stenosis	☐ Mitral insufficiency
	☐ Native valve	☐ Previous mitral valve replacement (valve-in-valve referral)
Comments:		
☐ Referral for other valve procedure	☐ Pulmonary valve disease	
	☐ Tricuspid valve disease	

Centralized referral and efficient work-up

- TTE transferred electronically
- Cath (coronary, right heart, aortic root, iliofemoral)
- Assessment by
  - Nursing
  - Interventional cardiology
  - Cardiac surgery

- Tentative acceptance pending CT
  - gated cardiac and ilio-femoral angiogram

Vancouver THV program

Functional Assessment

ADLs	6/6	✓
IADLS	4/8	✗
Gait speed	9.4	✗
Hand grips	40/42	✓
MMSE	30/30	✓
Frailty	4/9	✓
Recommendation	yes	✓

As it was

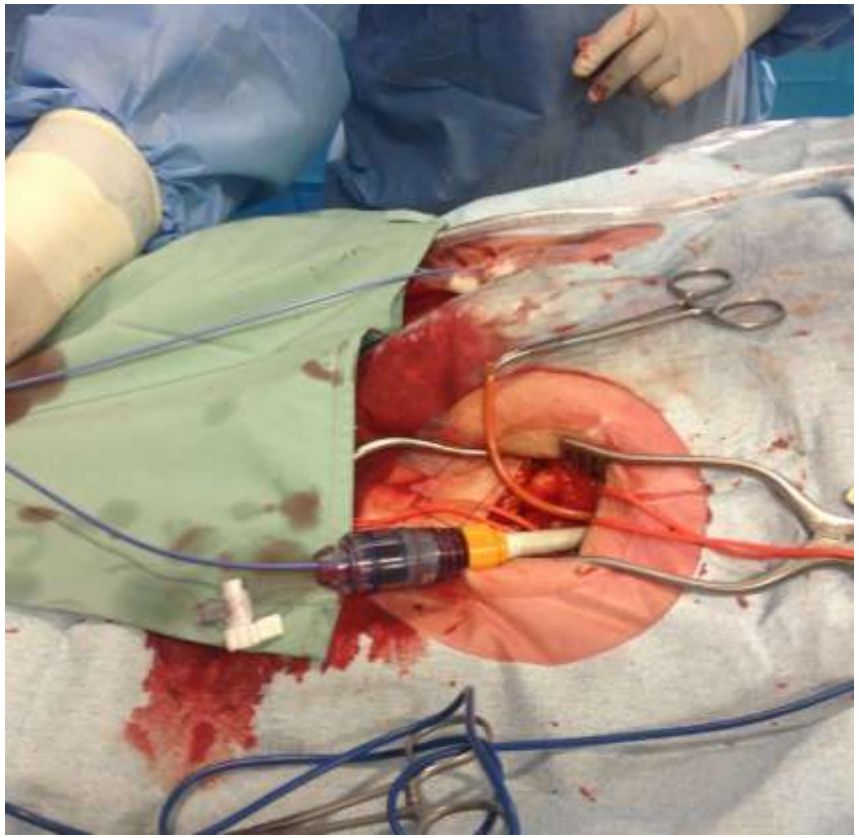
~15-20

Today

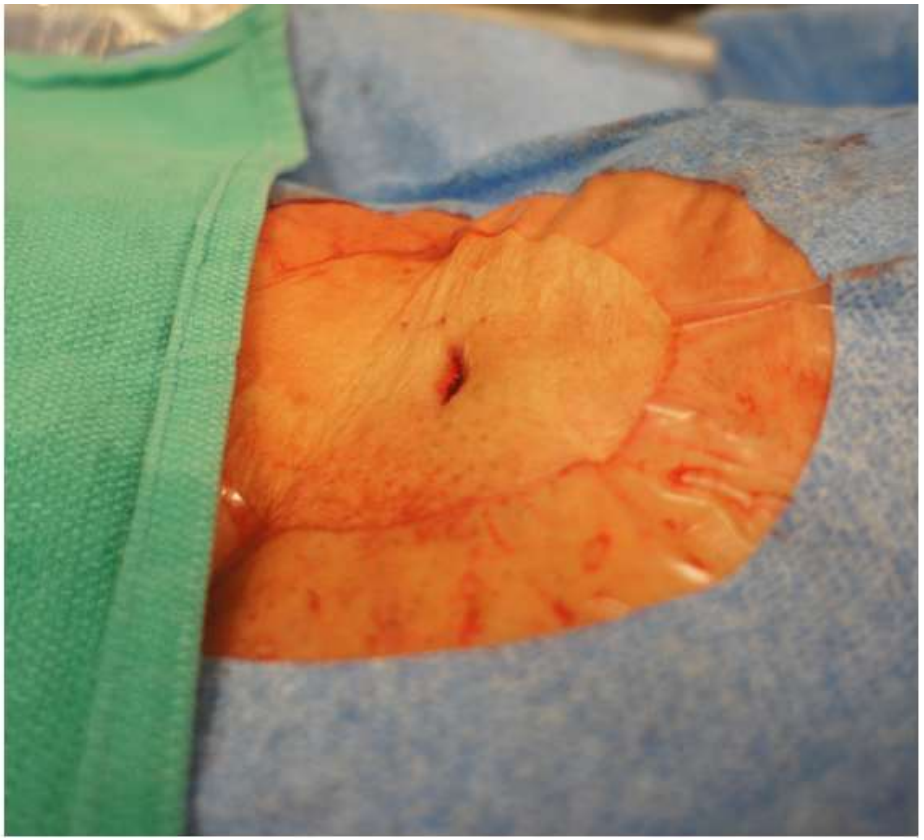
~7

Femoral access

Rare

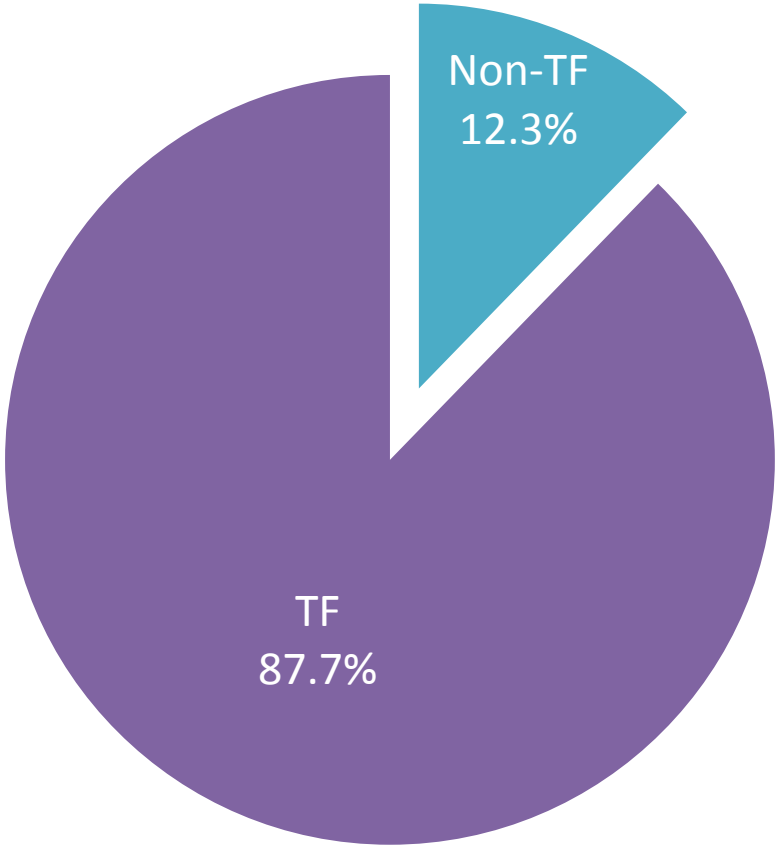


Standard

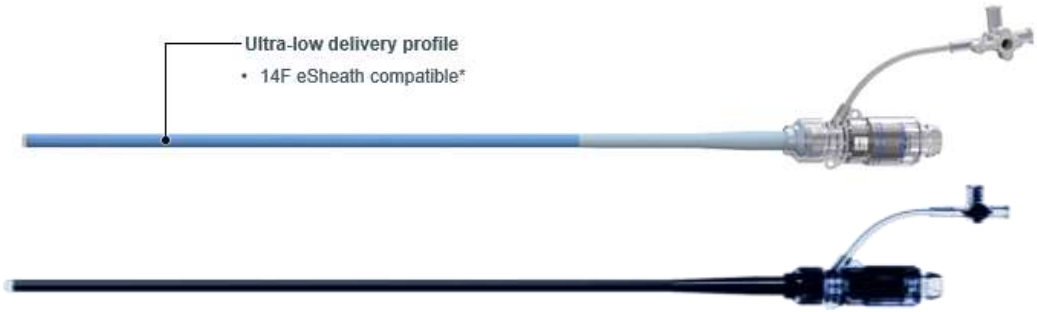


British Columbia TAVI Access

Jan 1, 2014 – May 31, 2015 (N=424)



Low profile sheaths are desirable



eSheath

Axela sheath

SoloPath sheath

In-Line sheath

Anesthetic management

- Cardiac anesthesiologist
- Standard physiologic monitoring
  - 5 lead EKG, O_2 Sat, Capnography, NIBP

- Arterial access:
  - low risk - share the femoral sheath
  - high risk - radial
- Venous access:
  - low risk - femoral
  - high risk - jugular or large peripheral line

- Sedation:
  - reassurance
  - warming
  - goal: anxiolysis; analgesia
  - maintain hemodynamic stability
  - avoid hypoventilation

Anesthetic management

- Generous local anesthesia
- Avoid benzodiazepines and long-acting narcotics
- Individualize

- Options:
  - Dexmedetomidine (0.1-0.5 ug/kg/hr)
  - Propofol (10-50ug/kg/hr)
  - Remifentanil (0.01-1ug/kg/hr)

- Start infusions early to obtain steady state
- Avoid boluses

Avoid bladder catheterization

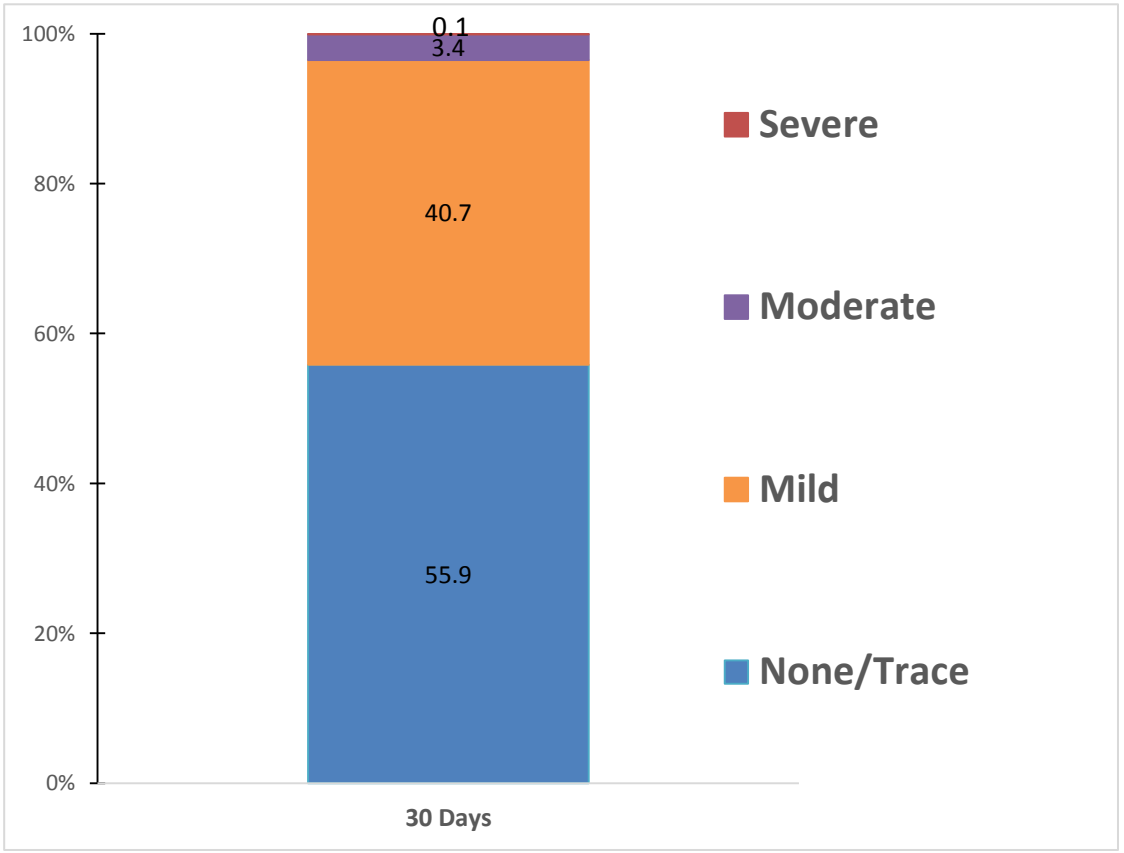
Vancouver 2011-2012

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

	Urinary catheter	No urinary catheter	p
Continuous bladder irrigation	2.7%	0%	0.03
Hematuria	17.6%	3.7%	0.001
Urinary tract infection	6.1%	1.4%	0.01
Intermittent catheterization post-procedure	8.9%	18.8%	0.03

With newer valves and CT sizing severe leaks can be infrequent

1/1,000

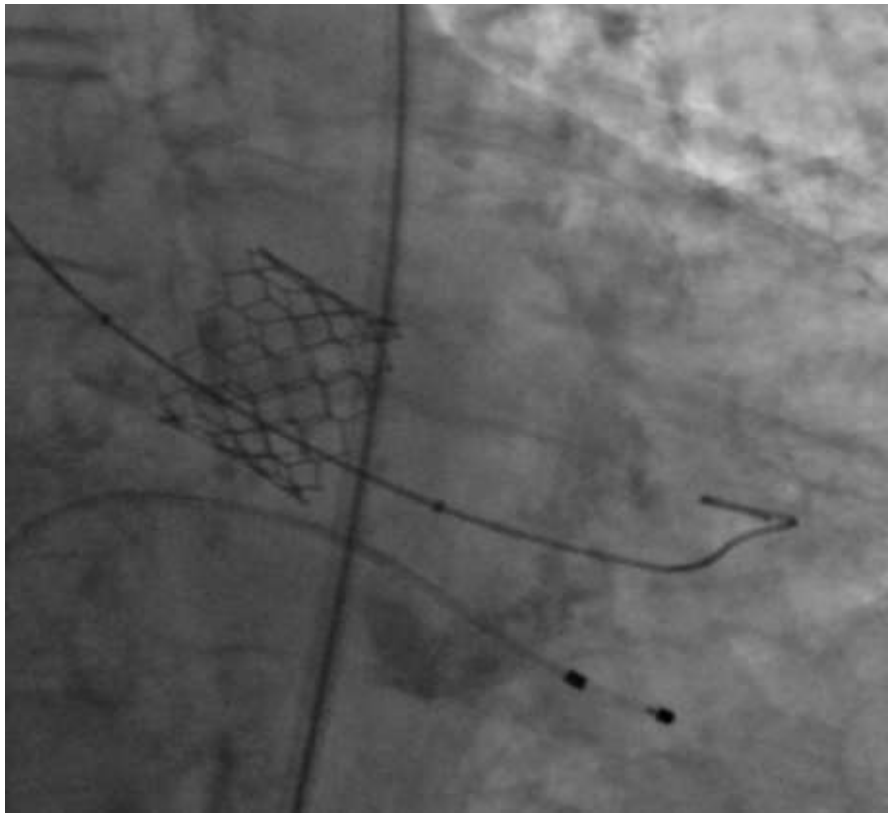


PARTNER II SAPIEN 3: High and Intermediate risk, 30 day TTE

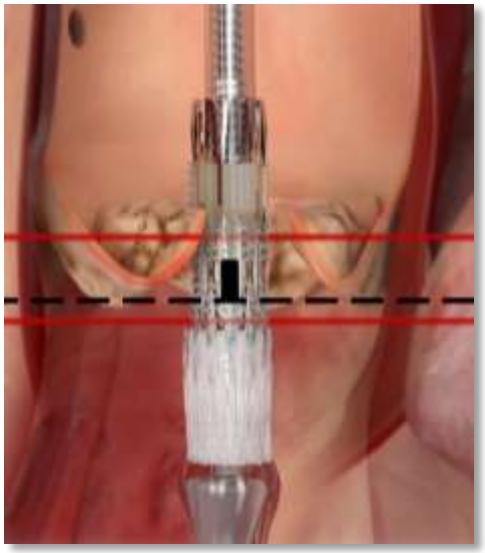
“Adjustable over-sizing” strategy for SAPIEN XT

1. Pick a valve that is larger than the annulus
2. Under fill if concerned
3. Redilate at nominal volume if necessary

“Adjustable” undersizing strategy for SAPIEN 3



Pacemakers are routinely removed in the lab



FIH SAPIEN 3 5 years ago

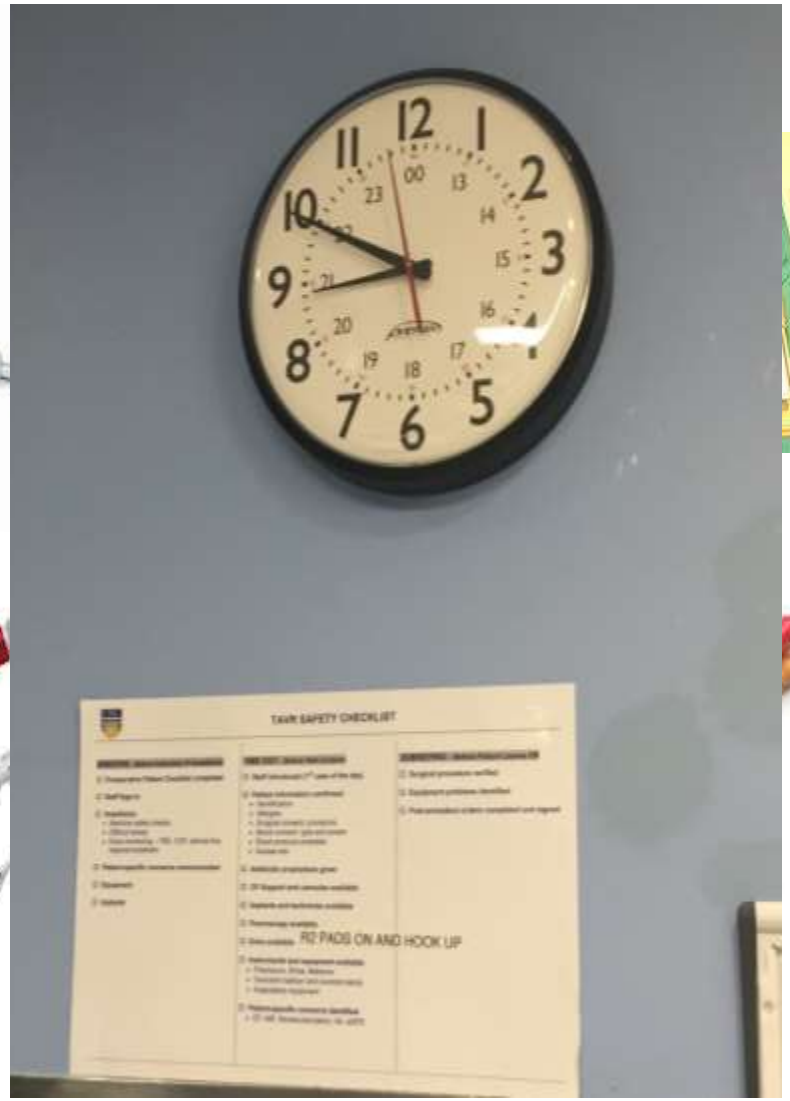
Feb 11, 2016 email:

- “The new pacemaker rate for all aortic pts was SXT 6.3% vs S3 4.1%. “

Valve characteristics desirable for early discharge

	SXT	S3	CV	Portico	Lotus
Low profile sheath	+	++	+	+	-
Leaks ≥moderate infrequent	+	++	+	-	++
AV block infrequent	++	+	-	+	-

An efficient, less-invasive procedure



- Admit in AM
- No GA
- No TEE
- No urinary catheter
- No PA catheter
- No pacemaker post-implant
- No cut-down

Standard vs accelerated pathway

Mostly SAPIEN XT

Variables	All n=393	Standard Discharge n=243 (61.8%)	Early Discharge n=150 (38.2%)	P
Length of stay*	3 (2,4)	3 (3,4)	1 (1,2)	<0.001
30-day mortality	5 (1.3%)	4 (1.6%)	1 (0.7%)	0.07
30-day re-admission	42 (10.7)	30 (12.3)	12 (8.0)	0.21
Disabling stroke	3 (0.8)	3 (1.2)	0	0.29
Bleeding				
Life threatening bleed	3 (0.8)	3 (1.2)	0	0.29
Major bleed	11 (2.8)	10 (4.1)	1 (0.7)	0.06
Minor bleed	7 (1.8)	6 (2.5)	1 (0.7)	0.26
Blood transfusion ≥ 1 Unit	26 (6.6)	22 (9.1)	4 (2.7)	0.013
Major vascular complication	5 (1.3)	5 (2.1)	0	0.16
New dialysis	1 (0.3)	1 (0.4)	0	1
Peri-procedural myocardial infarction	0	0	0	
New permanent pacemaker	27 (6.9)	23 (9.5)	4 (2.7)	0.01
Discharged home	384 (97.7)	234 (96.3)	150 (100)	0.017

Clinical Research

Risk Stratification and Clinical Pathways to Optimize Length of Stay After Transcatheter Aortic Valve Replacement

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

Standardized multidisciplinary practice

Nursing practice standard

NURSING CARE STANDARDS – PROTOCOL
NCS6377 – Transfemoral Transcatheter Aortic Valve Implantation (TF-TAVI)

Transfemoral, Transcatheter Aortic Valve Implantation, Post-procedure Care, protocol for (PHC)

Site Applicability

PHC: Cardiac Critical Care (CICU, CSICU) & Cardiac wards
VGH: VGH Cardiac Cath Lab & CCU

Skill Level
RN: Advanced skill
Cardiac monitoring skills; critical care nursing skills required for immediate post-operative period

Need to Know
Aortic stenosis (AS) is a narrowing of the aortic valve orifice. Valve replacement is the treatment of choice of severe AS. Surgical aortic valve replacement (SAVR) is the established surgical approach. Transcatheter aortic valve implantation (TAVI) is a minimally invasive option. TAVI can be performed using a transfemoral (TF) approach (i.e. through the femoral artery) or a non-TF approach (e.g. transapical, direct aortic). The prosthetic aortic valve is delivered via an arterial sheath and is placed within either a native aortic valve or within a previously replaced aortic valve as a valve-in-valve (ViV) (see Table 1).

Practice Guideline

Initial post-procedure assessment TF-TAVI

INITIAL NURSING ASSESSMENT	INTERVENTIONS
Immediately following patient's arrival into the CICU/cardiac care recovery area, the RN will assess and document: Neurological status: GCS, stroke assessment. ○ Ask patient to smile; inspect for facial symmetry or changes from baseline ○ Note speech characteristics; look for slurring ○ Ask patient to raise arms and grip; screen for asymmetrical weakness/numbness. ***If GA intra-procedure: In addition to above, assess RASS***	Use active re-warming to manage hypothermia (e.g. temperature less than 36°C) (PHC: see NCS5063 – Warming Blanket)

Published by: Providence Health Care, Vancouver, BC

TF TAVR physician orders

IF YOU RECEIVED THIS FAX IN ERROR, PLEASE CALL 604-500-3330 IMMEDIATELY

Providence HEALTH CARE **PRESCRIBER'S ORDERS**

NO DRUG WILL BE DISPENSED OR ADMINISTERED WITHOUT A COMPLETED
CAUTION SHEET
ALLERGY/INTOLERANCE STATUS FORM (PHC-PH041)

DATE AND TIME

TRANSCATHETER TRANSFEMORAL HEART VALVE IMPLANTATION POST-OP ORDERS
(Items with checkboxes must be selected to be ordered) Page 1 of 2

ADMISSION INSTRUCTIONS: Admit to critical care under Dr _____ Most responsible fellow: _____

CODE STATUS: Full code

OR

☐ Refer to completed Do Not Attempt Resuscitation (DNAR) and Options for Care Orders (PHC-PH254)

MONITORING: Cardiac monitoring for 5 days or until discharge – Class I x 18 hours; Class II until discharge or POD 5
Vital signs
☐ GA used intraprocedure: Q15MIN x 4, Q30MIN x 2, Q1H x 4, Q4H x 4, then routine
☐ Procedure done awake: Q15MIN x 4, Q1H x 4, Q4H x 4, then routine
Neurological assessment as per TF-TAVI nursing practice standard Q15MIN x 4, Q30MIN x 2, Q1H x 4, Q4H x 4 and then routine
Vascular access site assessment: Q15MIN x 4, Q30MIN x 2, Q1H x 4, Q4H x 4, then routine if groin stable. Notify interventional cardiology if groin unstable and/or change in clinical status
Remove arterial sheaths as per Cardiac Cath Lab: Post Procedure Care, protocol
Remove venous sheath as per Cardiac Cath Lab: Post Procedure Care, protocol
Remove central line(s) and monitoring lines 4 - 6 hours after the procedure if hemodynamically stable

Avoid urinary catheter. If present, remove as soon as possible (07:00 POD 1 at latest) if urine output greater than 30 mL/hour x 6 hours

DIET: NPO until hemostasis of site; sips of clear fluid and advance diet as tolerated
☐ Regular diet **OR** _____ ☐ Dysphagia assessment
☐ EF greater than 35%, encourage PO fluid intake (no restriction)

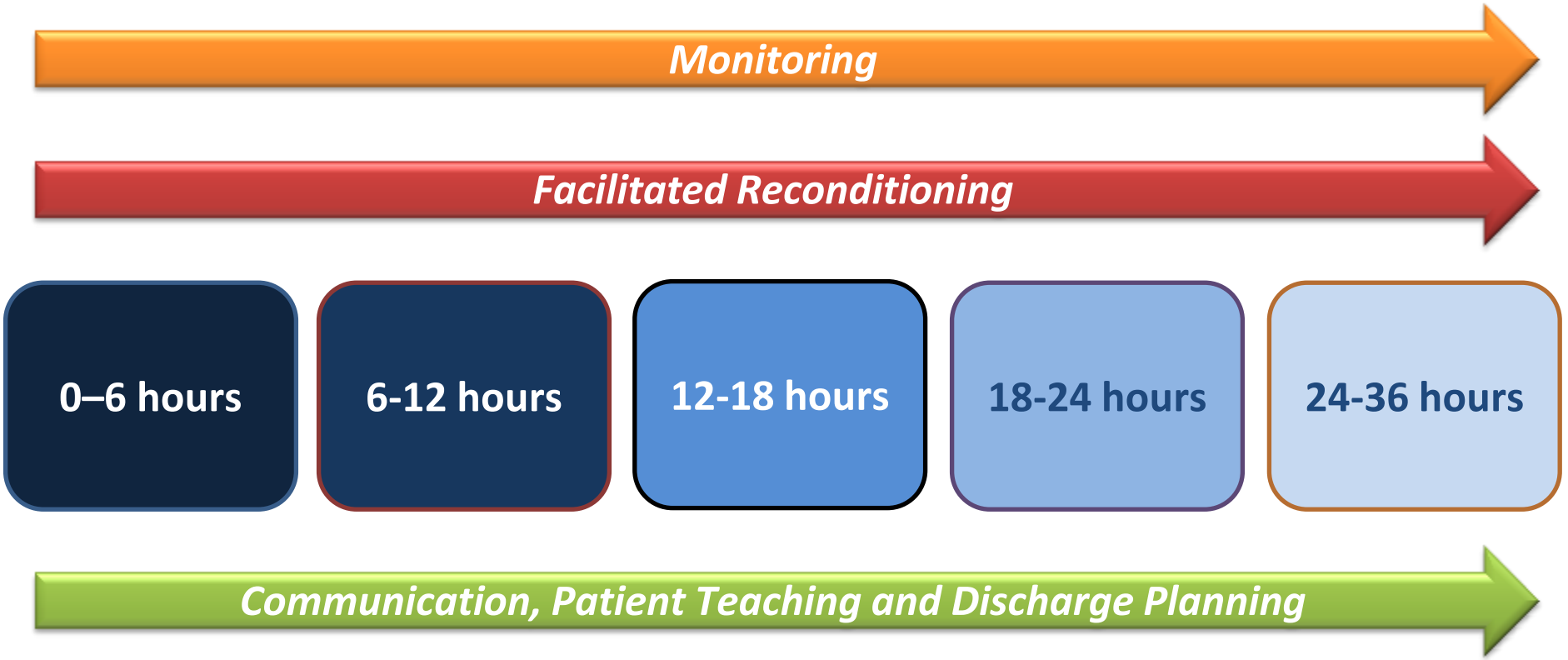
ACTIVITY: ☐ 4 hours bedrest: HOB flat x 2 hours; increase HOB to 30 degrees after 2 hours. If groin stable: progress mobility as per TF-TAVI Post-procedure care, nursing practice standard
OR
☐ 6 hours bedrest: HOB flat x 2 hours; increase HOB to 30 degrees after 2 hours and maintain bedrest for another 2 hours. If groin stable: progress mobility as per TF-TAVI Post-procedure care, nursing practice standard
OR
☐ 8 hours bedrest: HOB flat x 2 hours; increase HOB to 30 degrees after 2 hours and maintain bedrest for another 6 hours. If groin stable: progress mobility as per TF-TAVI Post-procedure care, nursing practice standard

LABORATORY: Post-procedure CBC, electrolytes, renal profile
POD 1 CBC, electrolytes, renal profile, BNP

DIAGNOSTICS: ECG post-procedure and daily x 3
Chest X-Ray on arrival to CICU (confirm line placement)
Echocardiogram (TTE) ☐ No TTE required
☐ Post procedure in CICU (procedure done under local anaesthesia)

Printed Name _____ Signature _____ College ID _____ Pager _____

Post-procedure standardized care: Making every hour count



Post-procedure standardized care

- **Monitoring:**
  - Critical care nursing x 8 hours
  - Priorities: Hemodynamic and neurological status, cardiac rhythm, vascular access hemostasis
  - Removal of invasive lines
- **Facilitated reconditioning:**
  - Nurse-led progressive activity protocol
  - Hydration, nutrition, elimination
- **Communication:**
  - Early alert to “stay on pathway”
  - Discharge planning with patient and family

TF TAVI: Monitoring

	0-6 Hours	6-12 Hours	12-18 Hours	18-24 Hours	24-36 Hours
Monitoring					
Vital signs	Q15 min x 4 Q1 hr x 3	Q4 hrs			
	Note: *If hypertensive in immediate post-procedure period, consider "watchful waiting" approach to facilitate return to baseline hemodynamic stability as directed by physician.*				
Cardiac rhythm	Continuous				
	Note: *Inform physician of any new intraventricular conduction dela*				
Vascular access	Q15 min x 4 Q1 hr x 3	Q4 hrs			
Neuro vital signs and Cincinnati Stroke Scale assessment	Q15 min x 4 Q30 min x 2 Q1 hr x 3	Q4 hrs			
Pain and discomfort	Assess and treat access site and/or back/ postural pain/discomfort as required.		N		
	Note: *Avoid opioids and sedative-hypnotics to minimize risk of deli effectiveness of repositioning and early mobilization*				
Lab work and tests	12-lead ECG. eGFR, CBC.	If local anaesthesia procedure and TTE not done at end of procedure: TTE (bedside in unit if possible).		12-lead ECG eGFR, CBC	
Invasive monitoring equipment	Avoid urinary catheter				
	Monitor central venous and peripheral arterial catheters as per standard protocols.	Remove central venous catheter. Remove peripheral arterial line.	Maintain peripheral IV saline lock.		Remove peripheral IV saline lock prior to discharge home.

- Critical care nursing x 8 hours
- **Priorities:** Hemodynamic and neurological status, cardiac rhythm, vascular access hemostasis
- Removal of invasive lines

TF TAVI: Facilitated reconditioning

	0-6 Hours	6-12 Hours	12-18 Hours	18-24 Hours	24-36 Hours
	Facilitated Reconditioning				
Mobilization and activity	Bedrest. Head of bed: • Flat x 2 hrs • Then ↑ at 30°	Implement progressive activity protocol: • Dangle to standing position at bedside. • Transfer to commode. • Mobilize short distance in room.	• Transfer to commode. • Up in chair for meals. • Mobilize short distance in room. • Encourage self-care behaviour. • Mobilize short distance outside of room. • Facilitate uninterrupted rest/sleep and return to diurnal cycle.		• Up in chair for meals. • Mobilize for 5-10 min every 4-6 hours. • Encourage self-care behaviour. • Facilitate rest.
Elimination	Assess need for elimination.	Mobilize to commode or to standing position.	Mobilize to commode and/or washroom.	Mobilize to washroom with assistance.	
	Note: *Anticipate low urine output in the early recovery period (usual low post-procedure fluid administration); Avoid urinary catheterization to minimize risk of UTI, urinary retention, hematuria and other complications; Consider intermittent catheterization if required (Max. x3).*				
Hydration	NPO until hemostasis and confirmed clinical stability. IV 50-75cc/hr.	• If LVEF ≥ 50%: Encourage fluids • If LVEF < 50%: Encourage			
Nutrition		Light dinner up in chair.	Up in ch Encour Goal: 3		

- Nurse-led progressive activity protocol
- Hydration, nutrition, elimination

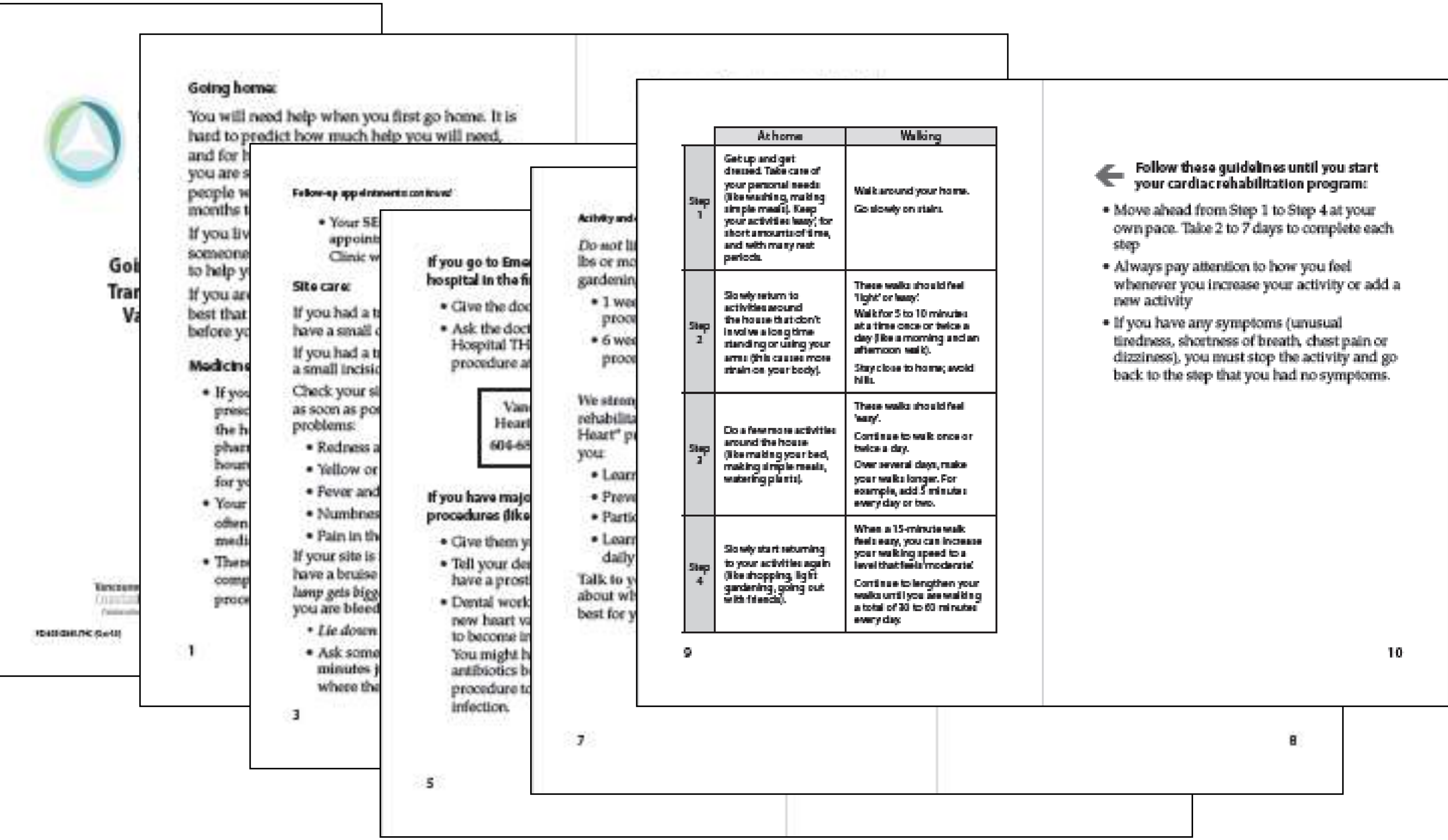
TF TAVI: Communication, patient teaching and discharge planning

Communication, Patient Teaching and Discharge Planning				
Communication		Communicate early with the multidisciplinary team any clinical variables that may impact goals of care and to identify opportunities to maintain patient on clinical pathway.		
Patient teaching	Provide patient teaching about maintaining vascular hemostasis	Provide coaching to support the facilitated reconditioning interventions (e.g., motivation for mobilization).	Begin discharge teaching.	Complete discharge teaching. Provide vascular access minor ooze dressing kit.
Discharge planning		Confirm discharge plan with patient and family.	Assess readiness for discharge.	Confirm discharge criteria.

- Early alert to “stay on pathway”
- Discharge planning with patient and family

Criteria driven discharge

☐	**Physician's order for discharge.** ***Consider multidisciplinary consensus for patient's readiness for discharge.***
☐	**Absence of persistent (> 3 hrs) intraventricular conduction delays.**
☐	**Absence of laboratory contraindications (i.e., clinically important change in hgb. and eGFR).**
☐	**Transthoracic echocardiogram completed and reviewed *(if required).***
☐	**Return to baseline mobilization.**
☐	**Confirmed availability of family member or home health care staff (To stay with patient and assist during the initial 48 hrs after discharge).**
☐	**Discharge teaching completed.** ***Content to cover:*** • **Vascular access site care** • **Follow-up bloodwork and medical appointments** • **Indications for emergent care** • **Activity and exercise prescription** • **Telephone follow-up (confirmed contact information)**
☐	**Confirmed telephone follow-up plan (Site contact)**



	At home	Walking
Step 1	Get up and get dressed. Take care of your personal needs (like washing, making simple meals). Keep your activities 'easy', for short amounts of time, and with many rest periods.	Walk around your home. Go slowly on stairs.
Step 2	Slowly return to activities around the house that don't involve a long time standing or using your arms (this causes more strain on your body).	These walks should feel 'light' or 'easy'. Walk for 5 to 10 minutes at a time once or twice a day (like a morning and an afternoon walk). Stay close to home; avoid hills.
Step 3	Do a few more activities around the house (like making your bed, making simple meals, watering plants).	These walks should feel 'easy'. Continue to walk once or twice a day. Over several days, make your walks longer. For example, add 5 minutes every day or two.
Step 4	Slowly start returning to your activities again (like shopping, light gardening, going out with friends).	When a 15-minute walk feels easy, you can increase your walking speed to a level that feels 'moderate'. Continue to lengthen your walks until you are walking a total of 30 to 60 minutes every day.

9

Follow these guidelines until you start your cardiac rehabilitation program:

- Move ahead from Step 1 to Step 4 at your own pace. Take 2 to 7 days to complete each step
- Always pay attention to how you feel whenever you increase your activity or add a new activity
- If you have any symptoms (unusual tiredness, shortness of breath, chest pain or dizziness), you must stop the activity and go back to the step that you had no symptoms.

10

Communication, patient teaching and discharge planning

Patient and family education

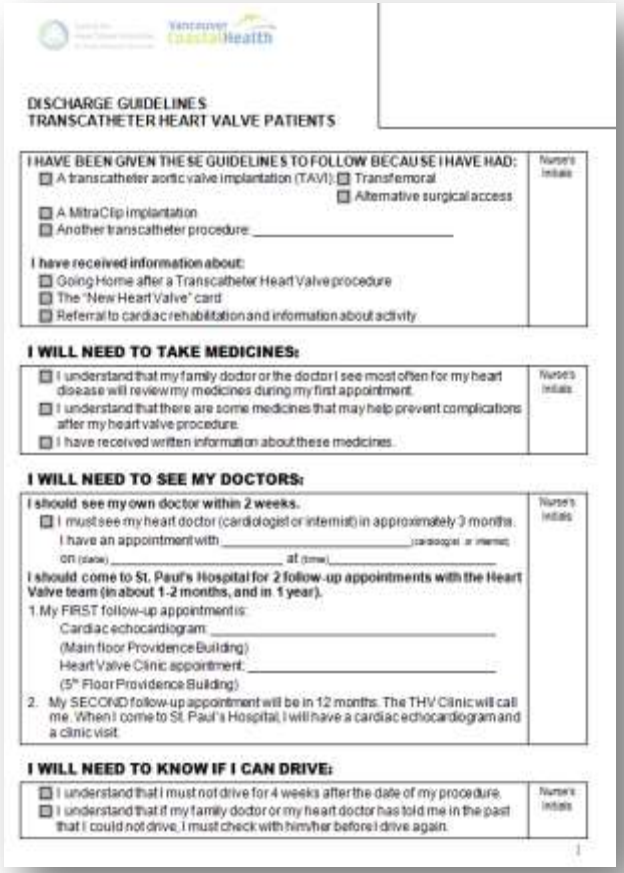
Multidisciplinary discharge guidelines

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

Going Home After a Transcatheter Heart Valve Procedure

Vancouver Coastal Health

Providence Health Care



Vancouver Coastal Health

DISCHARGE GUIDELINES
TRANSCATHETER HEART VALVE PATIENTS

I HAVE BEEN GIVEN THESE GUIDELINES TO FOLLOW BECAUSE I HAVE HAD: (Nurse's initials)
- ☐ A transcatheter aortic valve implantation (TAVI) ☐ Transfemoral ☐ Alternative surgical access
- ☐ A MitraClip implantation
- ☐ Another transcatheter procedure: _____

I have received information about:
- ☐ Going Home after a Transcatheter Heart Valve procedure
- ☐ The "New Heart Valve" card
- ☐ Referral to cardiac rehabilitation and information about activity

I WILL NEED TO TAKE MEDICINES: (Nurse's initials)
- ☐ I understand that my family doctor or the doctor I see most often for my heart disease will review my medicines during my first appointment.
- ☐ I understand that there are some medicines that may help prevent complications after my heart valve procedure.
- ☐ I have received written information about these medicines.

I WILL NEED TO SEE MY DOCTORS: (Nurse's initials)

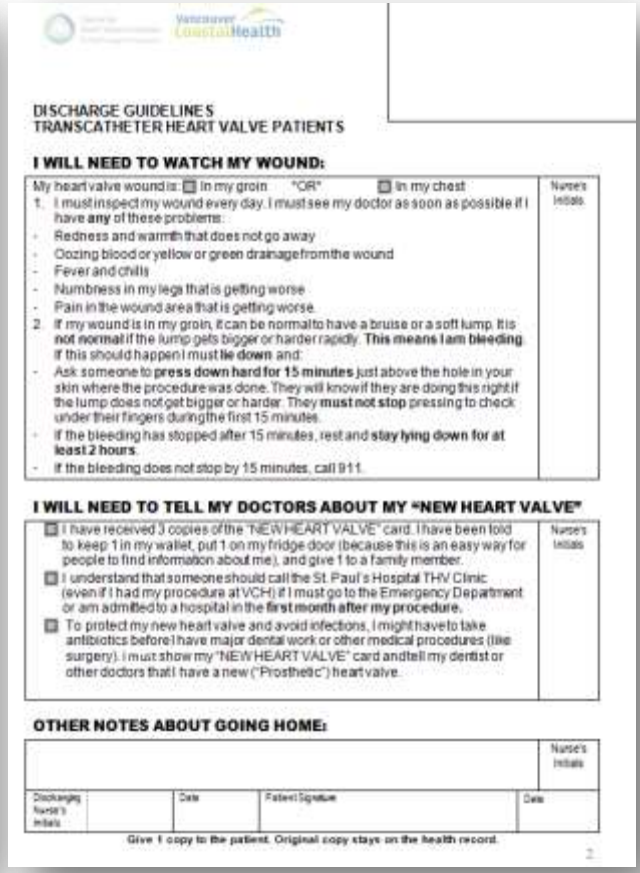
I should see my own doctor within 2 weeks.
- ☐ I must see my heart doctor (cardiologist or internist) in approximately 3 months.
  I have an appointment with _____ (cardiologist or internist)
  on (date) _____ at (time) _____

I should come to St. Paul's Hospital for 2 follow-up appointments with the Heart Valve team (in about 1-2 months, and in 1 year).

1. My FIRST follow-up appointments is:
   Cardiac echocardiogram: _____
   (Main floor Providence Building)
   Heart Valve Clinic appointment: _____
   (5th Floor Providence Building)
2. My SECOND follow-up appointment will be in 12 months. The THV Clinic will call me. When I come to St. Paul's Hospital, I will have a cardiac echocardiogram and a clinic visit.

I WILL NEED TO KNOW IF I CAN DRIVE: (Nurse's initials)
- ☐ I understand that I must not drive for 4 weeks after the date of my procedure.
- ☐ I understand that if my family doctor or my heart doctor has told me in the past that I could not drive, I must check with him/her before I drive again.

1



Vancouver Coastal Health

DISCHARGE GUIDELINES
TRANSCATHETER HEART VALVE PATIENTS

I WILL NEED TO WATCH MY WOUND: (Nurse's initials)

My heart valve wound is: ☐ In my groin "OR" ☐ In my chest

1. I must inspect my wound every day. I must see my doctor as soon as possible if I have **any** of these problems:
   - Redness and warmth that does not go away
   - Oozing blood or yellow or green drainage from the wound
   - Fever and chills
   - Numbness in my leg that is getting worse
   - Pain in the wound area that is getting worse.
2. If my wound is in my groin, it can be normal to have a bruise or a soft lump. It is **not normal** if the lump gets bigger or harder rapidly. **This means I am bleeding.** If this should happen I must **lie down** and:
   - Ask someone to **press down hard for 15 minutes** just above the hole in your skin where the procedure was done. They will know if they are doing this right if the lump does not get bigger or harder. They **must not stop** pressing to check under their fingers during the first 15 minutes.
   - If the bleeding has stopped after 15 minutes, rest and **stay lying down for at least 2 hours**.
   - If the bleeding does not stop by 15 minutes, call 911.

I WILL NEED TO TELL MY DOCTORS ABOUT MY "NEW HEART VALVE" (Nurse's initials)
- ☐ I have received 3 copies of the "NEW HEART VALVE" card. I have been told to keep 1 in my wallet, put 1 on my fridge door (because this is an easy way for people to find information about me), and give 1 to a family member.
- ☐ I understand that someone should call the St. Paul's Hospital THV Clinic (even if I had my procedure at VCH) if I must go to the Emergency Department or am admitted to a hospital in the **first month after my procedure.**
- ☐ To protect my new heart valve and avoid infections, I might have to take antibiotics before I have major dental work or other medical procedures (like surgery). I must show my "NEW HEART VALVE" card and tell my dentist or other doctors that I have a new ("Prosthetic") heart valve.

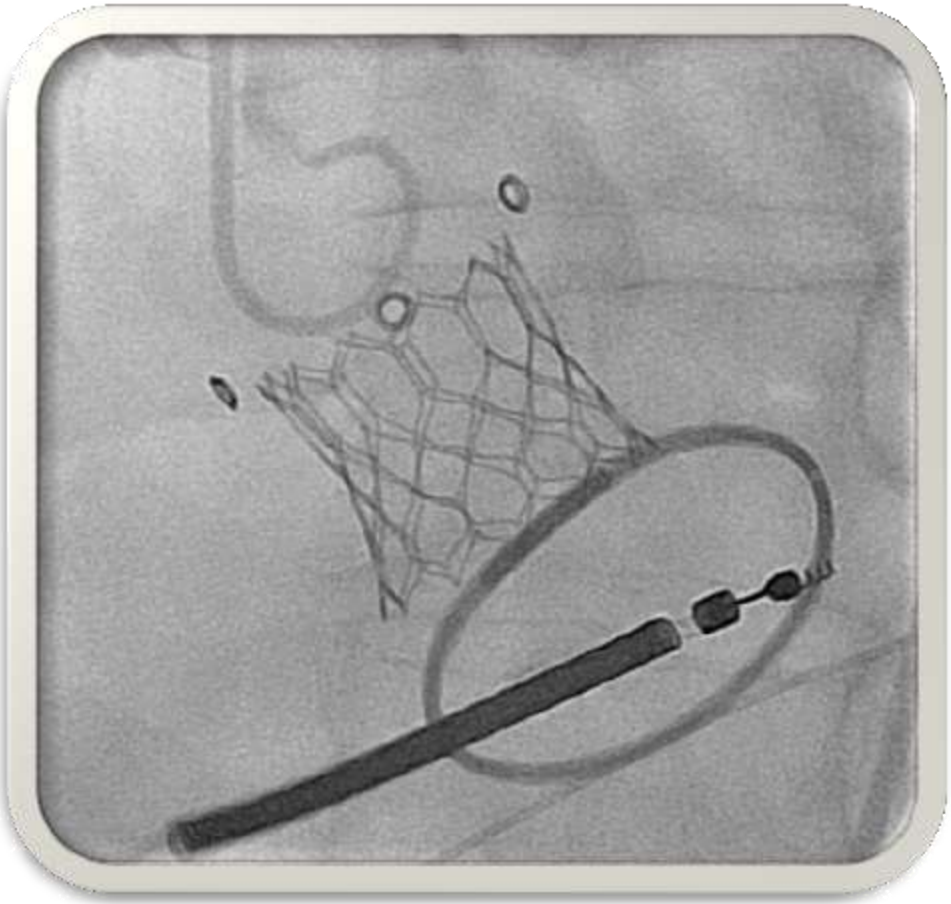
OTHER NOTES ABOUT GOING HOME:

				Nurse's initials
Discharging Nurse's initials		Date	Patient Signature	Date

Give 1 copy to the patient. Original copy stays on the health record.

2

Valve-inValve



- Conscious sedation
- No TEE
- Contrast not necessary
- Pre-dilation not necessary
- Negligible risk of
  - AV block
  - annular rupture
  - PV leak
- Next day discharge

NEWSLETTER

We have now enrolled 172 patients in the 3M TAVR Study with 90% of patients safely discharged home the following day and a 6.8% readmission rate at 30 days!

Site activations continue and new sites enroll patients!

Site	Enrolled
Centre Hospitalier de L'Université de Montréal	3
Calgary	1
Columbia	1
Hamilton General Hospital	3
Hôpital du Sacré-Cœur du Montréal	4
Mazankowski Alberta Heart Institute	1
Montreal Heart Institute	6
Sunnybrook Hospital	1
St. Michael's Hospital	12
St. Paul's Hospital	87
Toronto General Hospital	6
Vancouver General Hospital	47
Total	**172**

Project Contacts

Salima Jutha, CCRA
Project Manager
3M@icvhealth.ubc.ca

Dr. David Wood
Principal Investigator
David.Wood@vch.ca

Patients 49 and 50

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

SAPIEN 3 Ultra System: case #2

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

SAFE TAVR

Safety **A**nd **F**easibility of **E**arly Discharge Using the Portico Self-Expanding Prosthesis for Transfemoral **T**ranscatheter **A**ortic **V**alve **R**eplacement

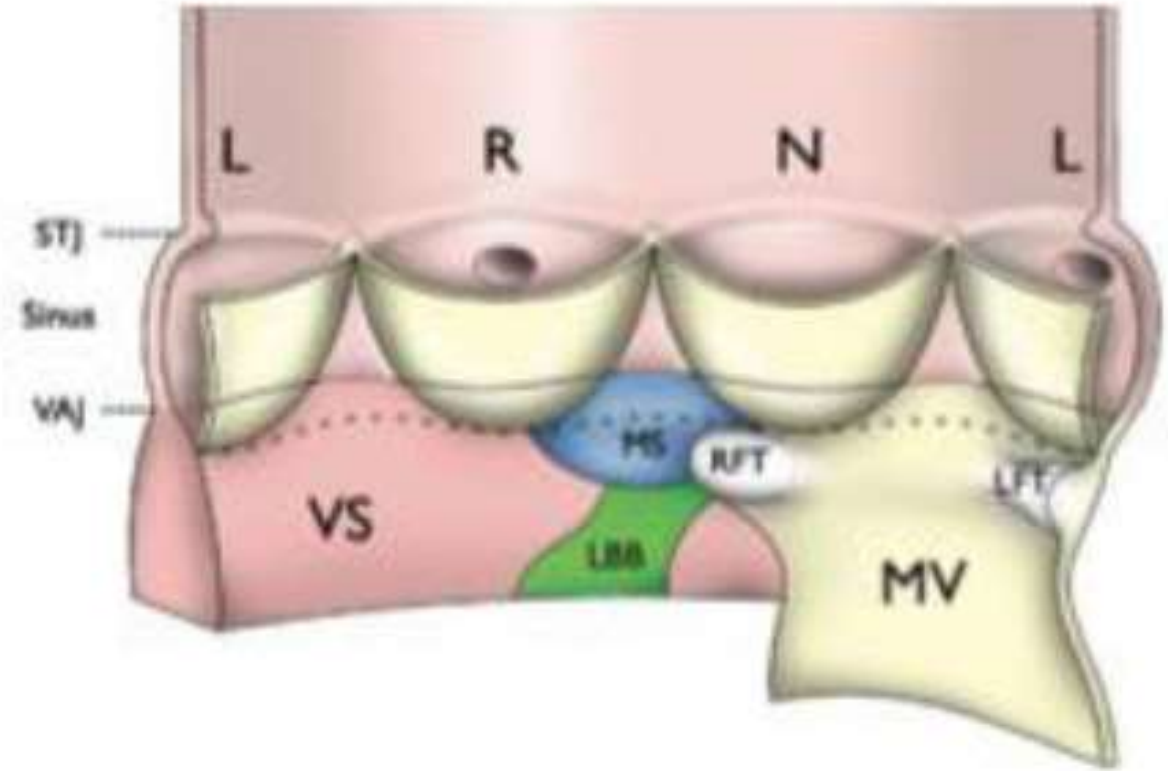
- 315 patients
- 15 sites
- Canada, US, Europe, Australia

- ***Primary Feasibility Endpoint***.
  - The proportion of patients undergoing elective transfemoral TAVR using the Vancouver Clinical Pathway who are discharged the next day

end

Next day discharge

AV block/pacemakers more frequent with low implantation



Igawa. Japanese Circulation

Vancouver TF TAVR post-procedure pathway (1)

	0-6 Hours	6-12 Hours	12-18 Hours	18-24 Hours	24-36 Hours
Monitoring					
Vital signs	Q15 min x 4 Q1 hr x 3	Q4 hrs			
	Note: *If hypertensive in immediate post-procedure period, consider "watchful waiting" approach to facilitate return to baseline hemodynamic stability as directed by physician.*				
Cardiac rhythm	Continuous			May discontinue for intermittent self-care	
	Note: *Inform physician of any new intraventricular conduction delay.*				
Vascular access	Q15 min x 4 Q1 hr x 3	Q4 hrs			Q8 hrs
Neuro vital signs and Cincinnati Stroke Scale assessment	Q15 min x 4 Q30 min x 2 Q1 hr x 3	Q4 hrs			
Pain and discomfort	Assess and treat access site and/or back/ postural pain/discomfort as required.		No pain/discomfort anticipated.		
	Note: *Avoid opioids and sedative-hypnotics to minimize risk of delirium; Resume patient's usual analgesia and/or sedation if possible; Maximize effectiveness of repositioning and early mobilization*				
Lab work and tests	12-lead ECG. eGFR, CBC.	If local anaesthesia procedure and TTE not done at end of procedure: TTE (bedside in unit if possible).		12-lead ECG eGFR, CBC	
Invasive monitoring equipment	Avoid urinary catheter				
	Monitor central venous and peripheral arterial catheters as per standard protocols.	Remove central venous catheter. Remove peripheral arterial line.	Maintain peripheral IV saline lock.		Remove peripheral IV saline lock prior to discharge home.
Facilitated Reconditioning					
Mobilization and activity	Bedrest. Head of bed:	Implement progressive activity protocol:			
		Dangle to standing position at bedside.	Transfer to commode. Up in chair for meals.		Up in chair for meals.

Vancouver TF TAVR post-procedure pathway (2)

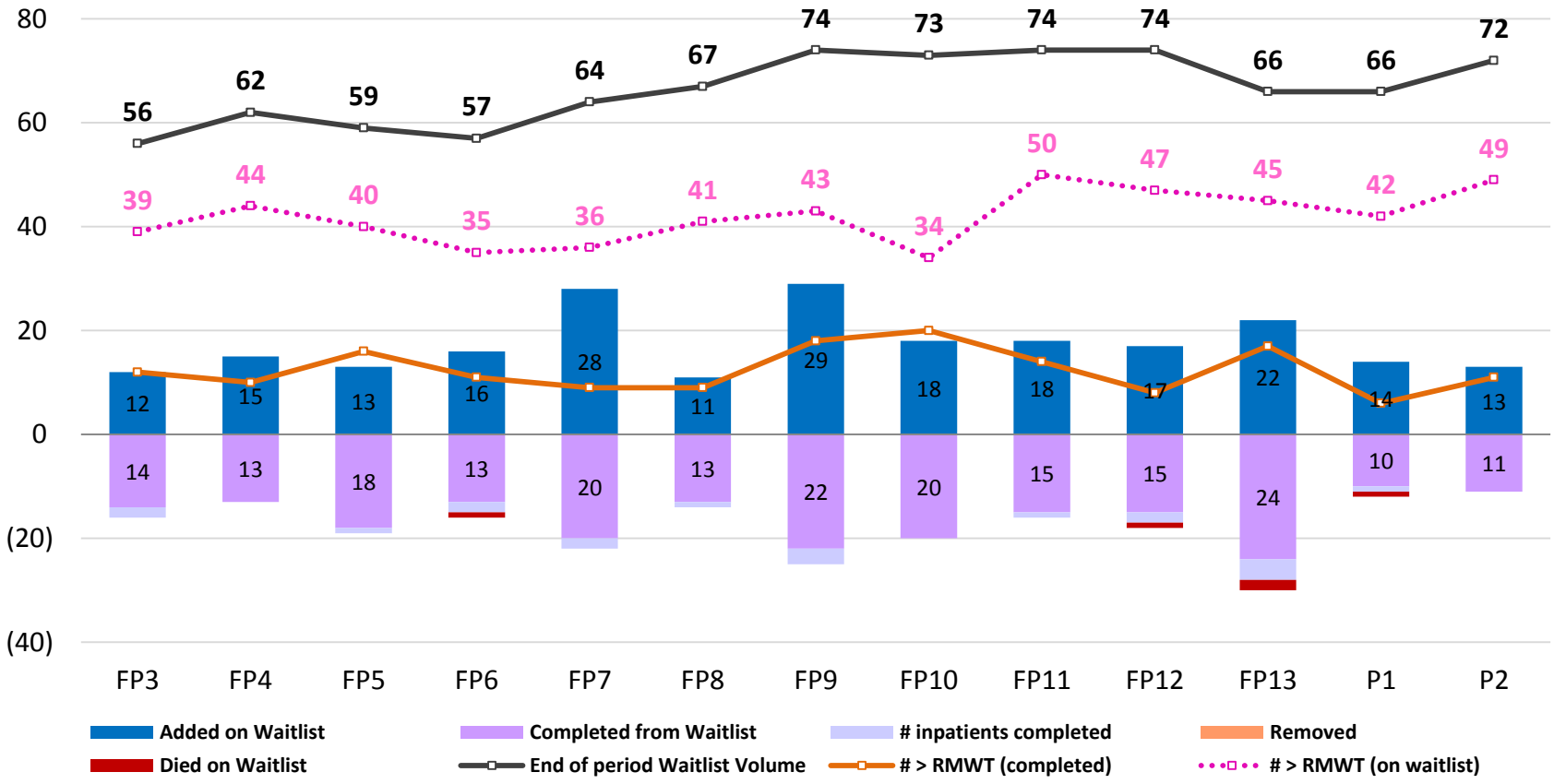
	0-6 Hours	6-12 Hours	12-18 Hours	18-24 Hours	24-36 Hours
	Flat x 2 hrs Then ↑ at 30°	Transfer to commode. Mobilize short distance in room.	Mobilize short distance in room. Encourage self-care behaviour. Mobilize short distance outside of room. Facilitate uninterrupted rest/sleep and return to diurnal cycle.		Mobilize for 5-10 min every 4-6 hours. Encourage self-care behaviour. Facilitate rest.
Elimination	Assess need for elimination.	Mobilize to commode or to standing position.	Mobilize to commode and/or washroom.	Mobilize to washroom with assistance.	
	Note: *Anticipate low urine output in the early recovery period (usual low peri-procedure fluid administration); Avoid urinary catheterization to minimize risk of UTI, urinary retention, hematuria and other complications; Consider intermittent catheterization if required (Max. x3).*				
Hydration	NPO until hemostasis and confirmed clinical stability. IV 50-75cc/hr.	If LVEF ≥ 50%: Encourage fluids. If LVEF < 50%: Encourage fluids within limit of pre-procedure fluid restrictions.			
Nutrition		Light dinner up in chair.	Up in chair for all meals. Encourage nutritional intake and preferred foods. Goal: 3 meals and 1-2 snacks/24 hours		
Communication, Patient Teaching and Discharge Planning					
Communication		Communicate early with the multidisciplinary team any clinical variables that may impact goals of care and to identify opportunities to maintain patient on clinical pathway.			
Patient teaching	Provide patient teaching about maintaining vascular hemostasis	Provide coaching to support the facilitated reconditioning interventions (e.g., motivation for mobilization). Begin discharge teaching.			Complete discharge teaching. Provide vascular access minor ooze dressing kit.
Discharge planning		Confirm discharge plan with patient and family.		Assess readiness for discharge.	Confirm discharge criteria.

Summary of Quality Improvement Changes during the Implementation of the Vancouver TAVR Clinical Pathway

	Historical Practice	TAVR Clinical Pathway Practice
PERI-PROCEDURE		
Location of procedure	Hybrid OR	Hybrid OR or CCL
Team		
Implanting physician(s)	Interventional cardiologists	
Anesthesiologist	In attendance	
Echocardiologist	Default strategy: TEE	Default strategy: TTE post-procedure
Nursing and allied health	2 OR RN, 1 CCL RN, 1 Radiology Technologist	If Hybrid OR: Unchanged If CCL: 3 CCL RN, 1 Radiology Technologist
Anesthesia	Default strategy: General anesthesia	Default strategy: Local anesthesia
Vascular access and closure	Percutaneous	
Venous access	Central venous catheter	Central venous catheter or use of side arm of femoral venous sheath
Temporary pacemaker	Default strategy: Removed at end of procedure if absence of contraindication	
Urinary catheter	Default strategy: Inserted	Default strategy: Not inserted
POST-PROCEDURE		
Location of recovery	CICU/CCU	CICU/CCU or Cardiac intervention unit (CCL recovery area)
Nursing	Critical care competencies	
Mobilization	Bedrest time 8 hours; routinely mobilized POD1	Bedrest time 4-6 hours; routinely mobilized POD0
Reconditioning	Mobilization, hydration, nutrition according to standard CICU practice and nursing discretion; Removal of urinary catheter on POD1	Standardized and prescribed Mobilization, hydration, nutrition; Avoidance of urinary catheterization
Critical care LOS	24-48 hours	< 24 hours
Expected LOS	3-5 days	1-3 days

Vancouver TF TAVI Wait List

May22/2015 – May19/2016



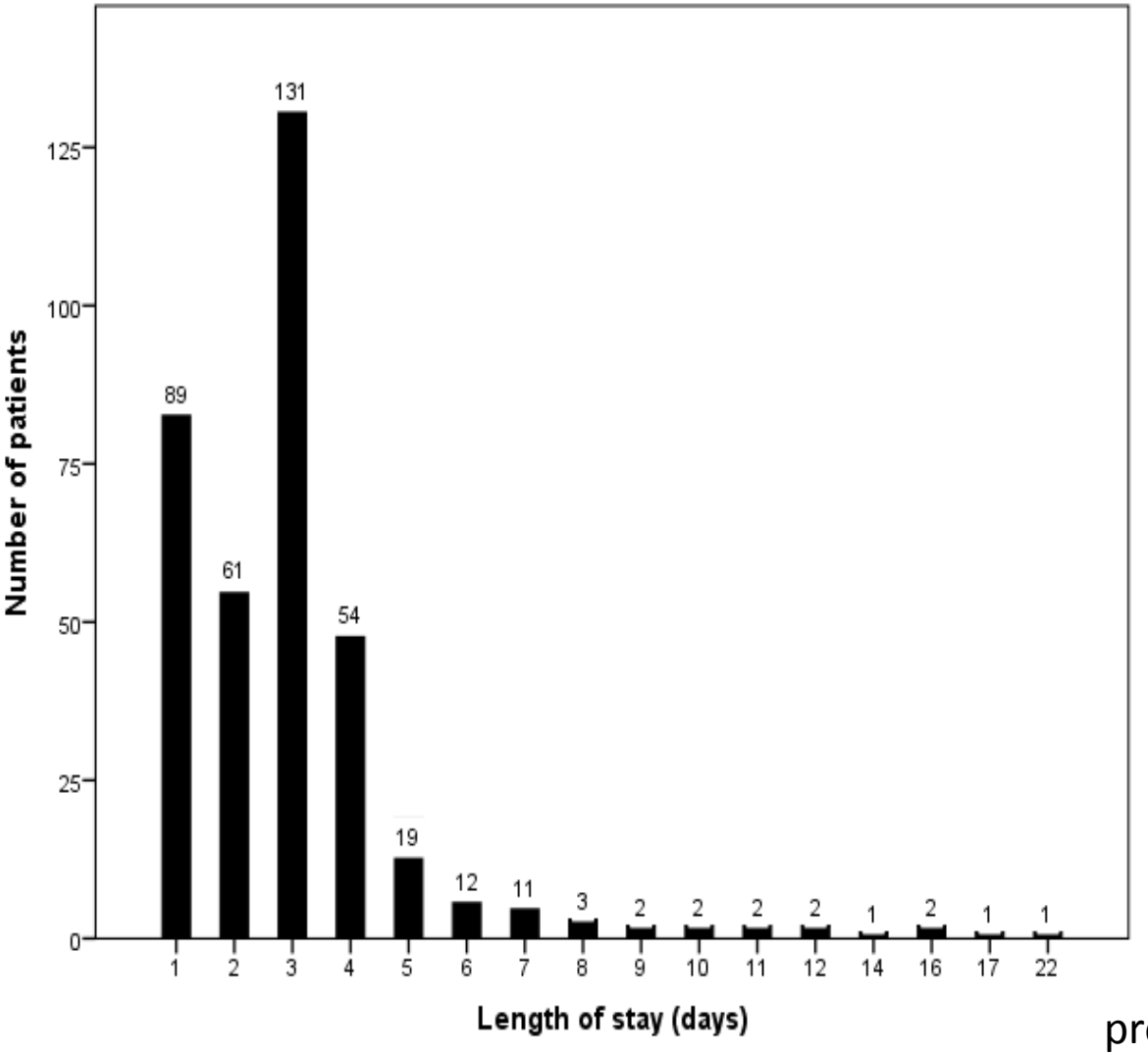
*Recommended maximum wait time defined as <42 days

Vancouver TAVR Clinical Pathway
Discharge Criteria

Monitoring
Completion and review of post-procedure transthoracic echocardiogram to confirm acceptable bioprosthetic hemodynamics with absence of delayed complications.
Absence of persistent intraventricular conduction delay.
Absence of vascular access site complications.
Absence of laboratory contraindications. If Hgb < 100 g/L and/or eGFR < 30 ml/min, obtain and review out-patient bloodwork 2 and 4 days after discharge.
Facilitated Reconditioning
Return to baseline mobilization.
Absence of elimination issues (e.g., urinary retention).
Communication
Multidisciplinary agreement of safety of discharge.
Confirmation of discharge plan with patient/family.
Confirmation of availability of social support during the initial 48 hours following discharge.
Completion of verbal discharge teaching and confirmation of patients/family's understanding of the discharge guidelines; Provision of written discharge education resources and prescription of medications.

Post-procedure length of stay

May 2012 - Oct 2014



procedure day = Day 0

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

3M TAVR

Vancouver 3M Post-Procedure Clinical Pathway

Facilitating Safe and Rapid Discharge Home

Goals of care:

1. Facilitated rapid return to baseline status
2. Safe next day discharge home
3. Seamless transition to support on-going recovery/reconditioning at home

	0-6 Hours	6-12 Hours	12-18 Hours	18-24 Hours	24-36 Hours
			Monitoring		
Vital signs	Q15 min x 4 Q1 hr x 3	Q4 hrs	Q4 hrs	Q4 hrs	Q4 hrs
	Note: *If hypertensive in immediate post-procedure period, consider "watchful waiting" approach to facilitate return to baseline hemodynamic stability as directed by physician.*				
Neuro vital signs	Q15 min x 4 Q30 min x 2 Q1 hr x 3	Q4 hrs	Q4 hrs	Q4 hrs	Q4 hrs
Cardiac rhythm	Continuous	Continuous	Continuous	May discontinue for intermittent self-care.	May discontinue for intermittent self-care.
	Note: *Inform physician of any new intraventricular conduction delay.*				
Vascular access	Q15 min x 4 Q1 hr x 3	Q4 hrs	Q4 hrs	Q4 hrs	Q8 hrs
	Note: *See "3M TAVR Nursing Management of Hematoma and/or Bleeding"*				
Pain and discomfort	Assess and treat pain/discomfort as required: • Access site • Back/postural pain		No pain/discomfort anticipated.		
	Note: *Avoid opioids and sedative-hypnotics to minimize risk of delirium; Resume patient's usual analgesia and/or sedation if possible; Maximize effectiveness of repositioning and early mobilization*				

“Adjustable” oversizing strategy for SAPIEN XT

Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 10, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.10.054

Underexpansion and Ad Hoc Post-Dilation in Selected Patients Undergoing Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, MD,* Jonathon Leipsic, MD,* Ronald Binder, MD,* Danny Dvir, MD,* John Tan, MD,* Melanie Freeman, MBBS,* Bjarne Norgaard, MD,† Nicolaj Hansson, MD,† Anson Cheung, MD,* Jian Ye, MD,* Tae-Hyun Yang, MD,* Kasia Maryniak, MD,* Rekha Raju, MD,* Angus Thompson, MBBS, PhD,* Philipp Blanke, MD,* Sandra Lauck, PhD, RN,* David Wood, MD,* John Webb, MD*

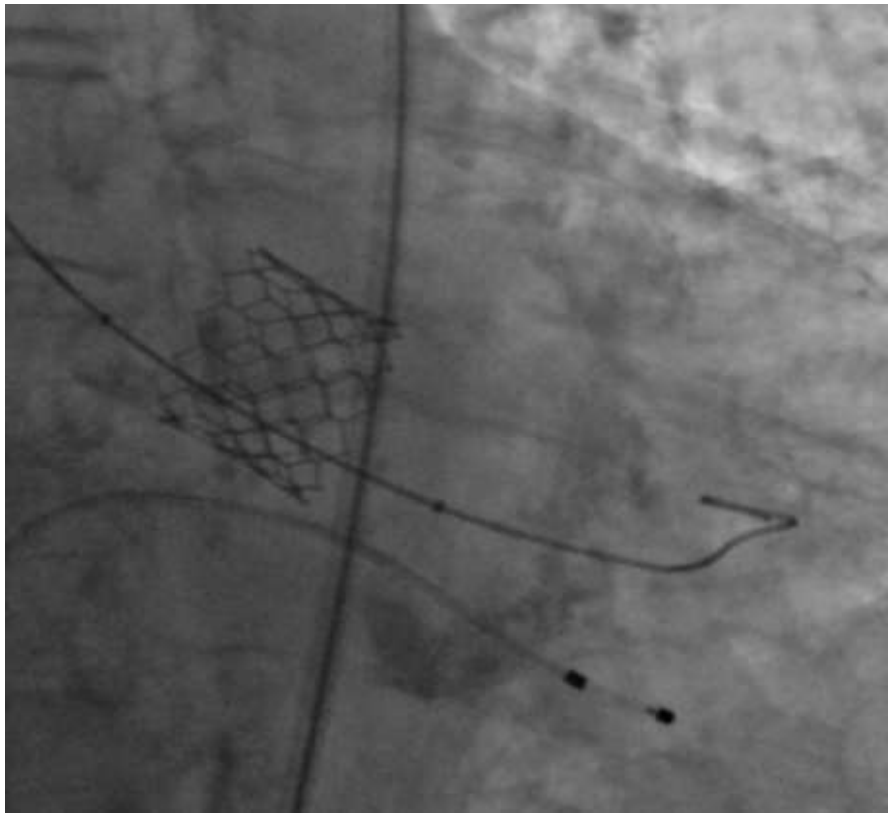
Vancouver, British Columbia, Canada; and Aarhus, Denmark

Adjustable Valve Sizing Strategy

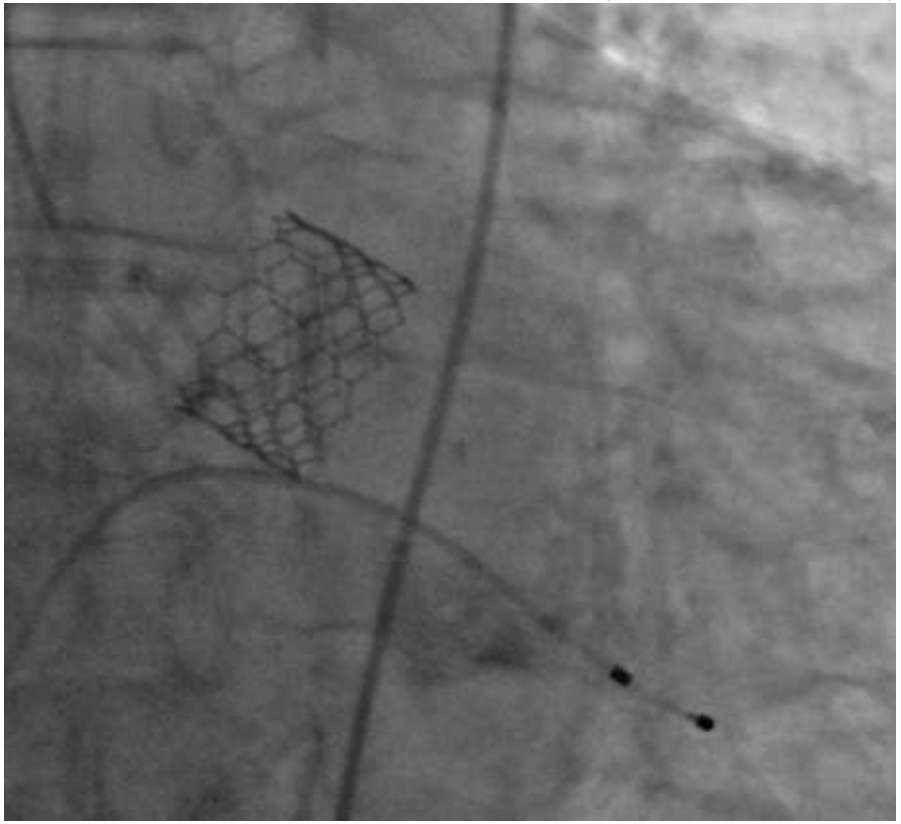
1. Pick a valve that is larger than the annulus
2. Under fill if concerned
3. Redilate at nominal volume if necessary

“Adjustable” under-sizing strategy for SAPIEN 3

SAPIEN 3 23mm THV (with a PV leak)



Post-dilated to 24mm (True balloon)



SAPIEN 3 can be dilated larger if needed