FEVAR REGISTRY
EARLY EXPERIENCE AND LESSONS LEARNT

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Background

- May 2015
  - *Lille*
- July 2015
  - *1st Proctored cases*
  - *Cape Town , Pretoria, & Johannesburg*
- Established FEVAR registry
- March 2020
  - *Formation of VASSA Complex Aortic Working Group*

Fevar registry

- All patients undergoing advanced aortic technologies (elective and emergency procedures)

  - *COOK devices*

- These included

  - *custom-made devices,*

    - fenestrated EVAR (FEVAR),

    - branched devices,

    - a combination of fenestrations and branches,

  - *Non-customized branch graft devices (4 generic branches).*

    - T-branch

63 patients underwent the FEVAR between Jul 2015 – Dec 2020

- Age
- Gender
- Ethnicity
- Location of aneurysm
- Type of aneurysm
- Graft design
- Graft characteristics
- **Case inside / outside instructions for use (IFU)**

- Time between graft design and implantation
- Stent graft specifications
- Outcomes:
- Technical success
- Perioperative morbidity
- Perioperative mortality
- Complications
- Secondary interventions
- Long-term mortality

"Outside IFU"

- Angulation of the Pt vessels
  - *(>60° infra renal >45° supra renal)*
- Access
  - *Small Femoral*
  - *Tortuous / Narrow Iliacs*
  - *Aortic bifurcation < 20 mm*
- In-situ EVAR stent from other devices
- Target vessels too close to each other
  - *(<15 min on clock position, <10 mm from each other)*
- Aortic diameter at the level of the renals = <20mm (can't do a 4 Fen)

Survival Outcomes

| Characteristic	Category	Overall		Outside IFU		Inside IFU		P-value
		n	%	n	%	n	%	
n				16		47		
Post intervention required (grouped)			6		6		6	>0.99
30-day Mortality			13		25		9	0.19
1-Year survival (%; 95% CI)		84 (72-91)		61 (33-81)		91 (79-97)		
3-year survival (%; 95% CI)		76 (61-86)		61 (33-81)		81 (63-91)		

The following significant differences between the IFU groups were found:

- All the dissections were in the Outside IFU group (38% vs 0%).

- The Outside IFU group
    - *higher prevalence of symptomatic cases (38% vs 6%)*
    - *higher incidence of emergency rupture before graft implantation(19% vs 2%).*

- The overall success rate was higher in the Inside IFU group (98% vs 74%)
    - *this was reflected in higher success rates for both fenestration and branch graft stents*

- The Outside IFU group suffered a higher rate of endoleaks (25% vs 4%).

- The patient survival of the Outside IFU group was poorer compared to that of the Inside IFU group (Hazard Ratio 3.02; 95% CI 1.09-8.38).
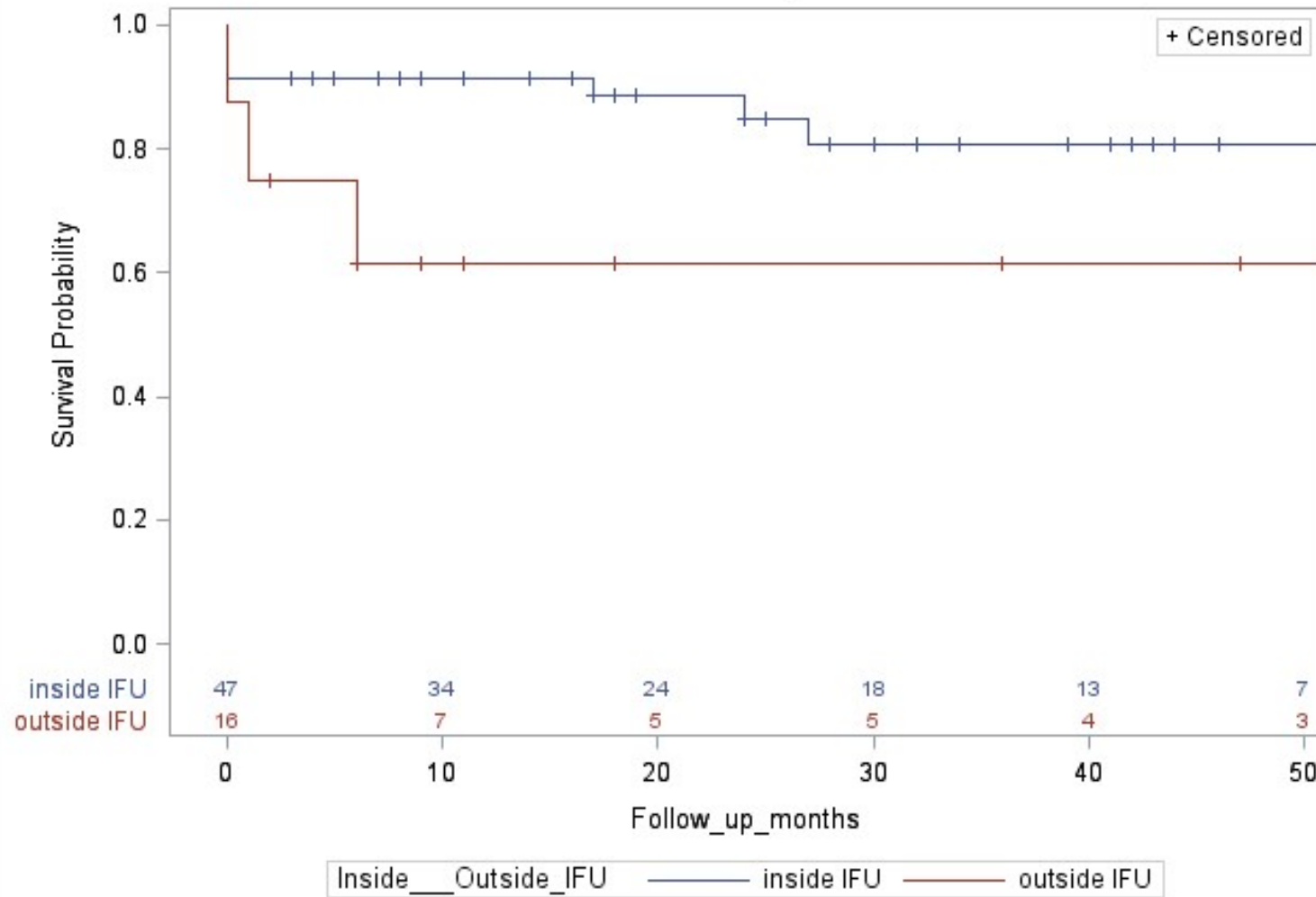
Product-Limit Survival Estimate
With Number of Subjects at Risk
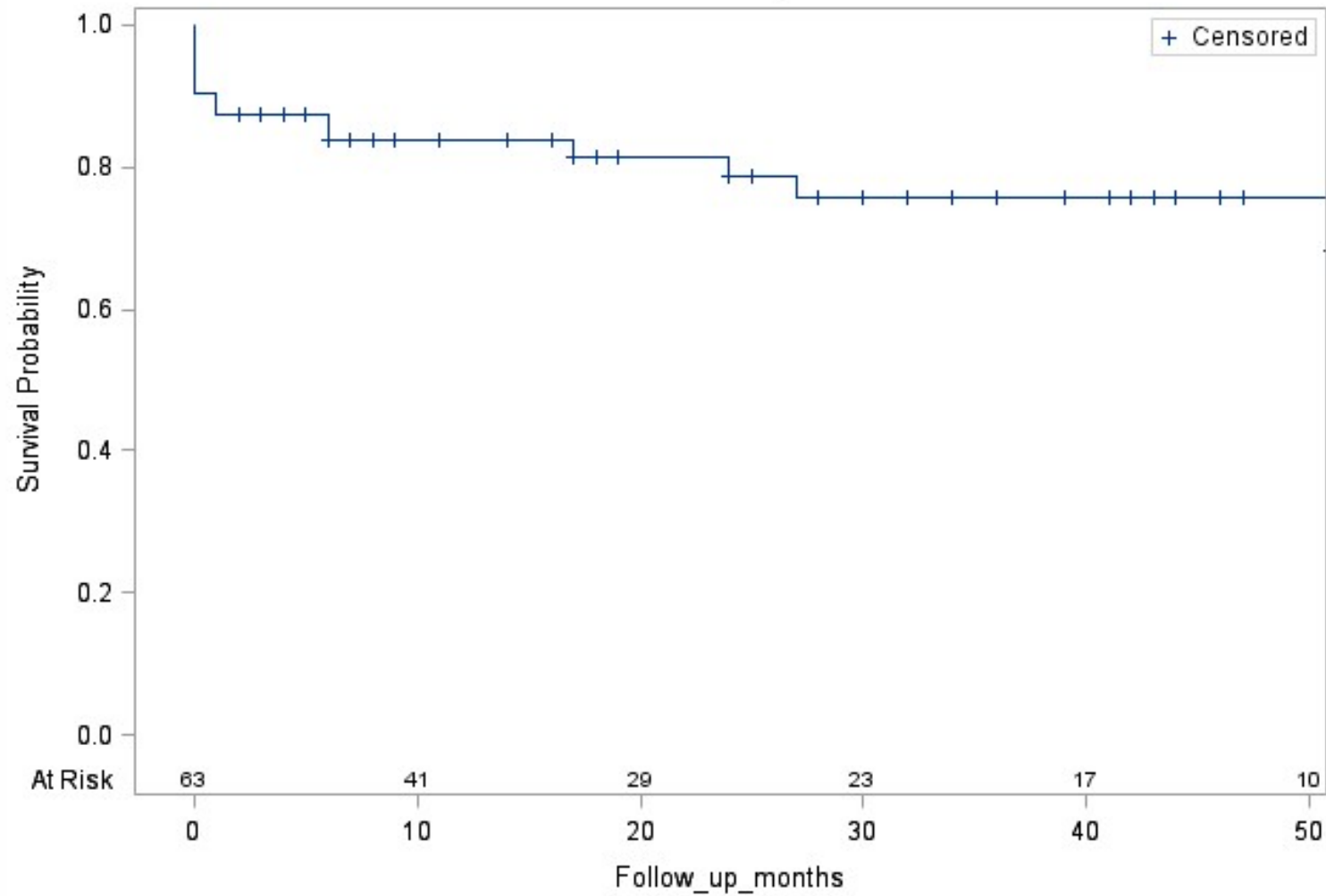
Product-Limit Survival Estimates
With Number of Subjects at Risk

TIME FOR REFLECTION

Unique challenges in the South African setting

- Patient selection,

- Technical considerations,

- Type and extent of pathology at hand

- Lack of Institutional expertise and experience

- Challenges associated with achieving timeous approval for funding such expensive technologies

- Long design and production times

- Lack of availability of hybrid theatre facilities (especially in the state hospital settings)
    - *Absence of high-volume aortic centers*

Patient selection / Device selection

- EVAR procedure of choice for high risk patients???

- The focus should rather be on predicted life expectancy rather than assessing whether patients are fit enough to survive the procedure.

- Most patients with juxtarenal / pararenal aneurysms would probably have an open repair if they are able to tolerate an aortic cross clamp.

- Those unable to undergo open surgery
  - *standard EVAR (for juxtarenal AAA's) with or without adjunctive devices (EndoAnchors)*
  - *Chimney EVAR*

- Only 49,2% juxtarenal aneurysms and only 13 patients with 3 or less fenestrations.

Selection dilemma

■ The resource constraints related to cost

■ Delays in customized graft production

■ Perform higher risk procedures during our early experience.

■ This registry includes

– *complex acute and chronic dissections,*

– *thoracoabdominal aneurysms, and*

– *ruptured thoracoabdominal aneurysms,*

– *and patients with type Ia endoleaks after previous EVAR*

FEVAR in juxtarenal and pararenal aneurysms are comparable to that of standard EVAR have much better outcomes when compared to FEVAR for thoracoabdominal aneurysms and dissections

Inside IFU vs Outside IFU

- In this cohort we had 25,4% (16) performed outside IFU with poorer results when compared to patients inside IFU.

    - *technical success of 73,7%*

    - *peri-operative mortality of 25%.*

- Most of these patients who are unfit for an open thoracoabdominal aneurysm repair

- No high-volume centers for open thoraco-abdominal repairs in South Africa.

Results are encouraging when put into perspective comparing them to open repairs in patients unfit for surgery

The South African Landscape

- Two-tiered healthcare system

- We are rated as the 37th richest country
  - *49,2% of our adult population living below the upper poverty line.*

- Unemployment rate is at an all-time high (34.4%)

- Growth at less than 1%

- More insured people are buying down

- National Health Insurance

- High turn down rate for FEVAR procedures in both state and private sectors with
  - *3 procedures being performed in the state sector.*
  - *63 of 149 approved*

COMPARING ERAS

Before December 2020 vs After December 2020

Group Demographics

Characteristic	Category	Overall		Inside IFU				Outside IFU			
				Era 1 (2015-2020)		Era2 (2021-2023)		P-value	Era1 (2015-2020)		Era 2 (2021-2023)		P-value
		n (133)	%	n (47)	%	n (60)	%		n (16)	%	n (10)	%	
Age (years): median (IQR)		71 (66-77)		72 (68-87)		70 (64-75)		0.059	72 (62-80)		75 (55-77)		0.88
Gender	Male	85		94		78		0.031	88		90		>0.99
	Female	14		6		22			13		10		
Ethnicity	White	83											
	Black	8											
	Coloured	2											
	Indian	5											
Ethnicity (grouped)	White	83		89		78		0.19	88		80		0.63
	Other	17		11		22			13		20		
Risk Factors	Cardiac Disease	48		40		58		0.081	38		40		>0.99
	Respiratory Risks	45		28		62		0.0008	25		70		0.043
	Peripheral Vascular Disease	35		40		28		0.22	44		30		0.68
	Hypertension	23		28		23		0.66	6		30		0.26
	Renal Impairment	14		11		12		>0.99	25		20		>0.99
	HIV	12		11		13		0.77	6		20		0.54
	Smoking	11		19		7		0.073	0		20		0.17
	Hypercholesterolemia	9		13		5		0.18	13		10		>0.99
	Cancer in remission, Diabetes, CABG, previous Stroke, Connective Tissue Disease	15											

Characteristics

Characteristic	Category	Overall		Inside IFU				Outside IFU			
				Era 1 (2015-2020)		Era2 (2021-2023)		P-value	Era1 (2015-2020)		Era 2 (2021-2023)		P-value
		n (133)	%	n (47)	%	n (60)	%		n (16)	%	n (10)	%	
Case Type	Aneurysm		91		98		98	>0.99		56		70	0.68
	Dissection		9		2		2			44		30	
Location of Aneurysm	Juxta-Renal		44		54		41	0.17		60		20	0.31
	Thoraco-Abdominal		26		28		29	>0.99		20		30	0.60
	Para-Renal		24		17		31	0.21		10		20	0.55
Crawford Classification by Type (n=121)	1		1										
	2		6										
	3		11										
	4		14										
	5		5										
	Unknown (0)		64										
Stanford Classification by Type (n=12 dissections)	A	1							1				
	B	9		1					6		2		
	Unknown (0)	2				1			1				
Other characteristics of case	Symptomatic		18		6		22	0.031		38		20	0.42
	Visceral Posterior Bulge		17		17		20	0.80		13		10	>0.99
	Emergency rupture before graft arrived		4		4		0	0.19		19		0	0.26

Outcomes & Technical Success

Characteristic	Category	Overall		Inside IFU						Outside IFU				
				Era 1 (2015-2020)		Era2 (2021-2023)		P-value		Era1 (2015-2020)		Era 2 (2021-2023)		P-value
		n (133)	%	n (47)	%	n (60)	%			n (16)	%	n (10)	%	
Stent graft specifications	Thoracic Component	33		26		32		0.53		50		50		>0.99
	Carotid Subclavian Bypass / Carotid Branch Bypass	3		2		3		>0.99		6		0		>0.99
	Staged	23		19		25		0.50		31		10		0.35
Technical Success	Overall (n=489 stents)	93		98		94		0.99		74		92		0.92
	Fenestration graft stents (n=367)	92		99		92		0.97		76		88		0.94
	Branch graft stents (n=122)	88		94		97		0.98		68		100		0.77
	Left renal successfully stented (n=130)	94		98		95		0.63		87		90		0.63
	Right renal successfully stented (n=127)	94		98		100		0.44		57		90		0.17
	ACC renal successfully stented (n=1)	100												
	SMA successfully stented (n=124)	98		98		100		0.43		87		100		0.50
	Coeliac successfully stented (n=107)	82		97		77		0.013		69		88		0.61
Complications	Endoleak	11		4		10		0.46		25		20		>0.99
	Adjunctive / Additional stenting	5		13		0		0.0059		6		0		>0.99
	Renal failure – Dialysis required	5		4		3		>0.99		13		10		>0.99
	Limb ischemia	3												
	Spinal Cord ischamia	2												
	Compartment syndrome	2												
	Bowel ischemia / Acalanes Cholecystitis	0												

Survival Outcomes

Characteristic	Category	Overall	Inside IFU		P-value	Outside IFU		P-value
			Era 1 (2015-2020)	Era2 (2021-2023)		Era1 (2015-2020)	Era 2 (2021-2023)	
		n (133)	%	n (47)	%	n (60)	%		n (16)	%	n (10)	%	
Number of post-interventions	0	86	85	87	0.45	88	90	>0.99
	1	10	11	13		0	0	
	2	2	2	0		6	10	
	3	2	2	0		6	0	
Post-intervention required (grouped)		14	15	13	>0.99	13	10	>0.99
30-day Mortality		8	9	5	0.70	25	0	0.14
1-year survival (%; 95% CI)		87 (79-92)	87 (74-94)	95 (85-98)	0.93	56 (30-76)	100 (not est.)	0.069
2-year survival (%; 95% CI)		83 (74-89)	85 (71-93)	85 (64-94)		56 (30-76)	Not estimable	
3-year survival (%; 95% CI)		78 (68-85)	81 (66-89)	Not estimable		56 (30-76)	Not estimable	

Product-Limit Survival Estimates
With Number of Subjects at Risk
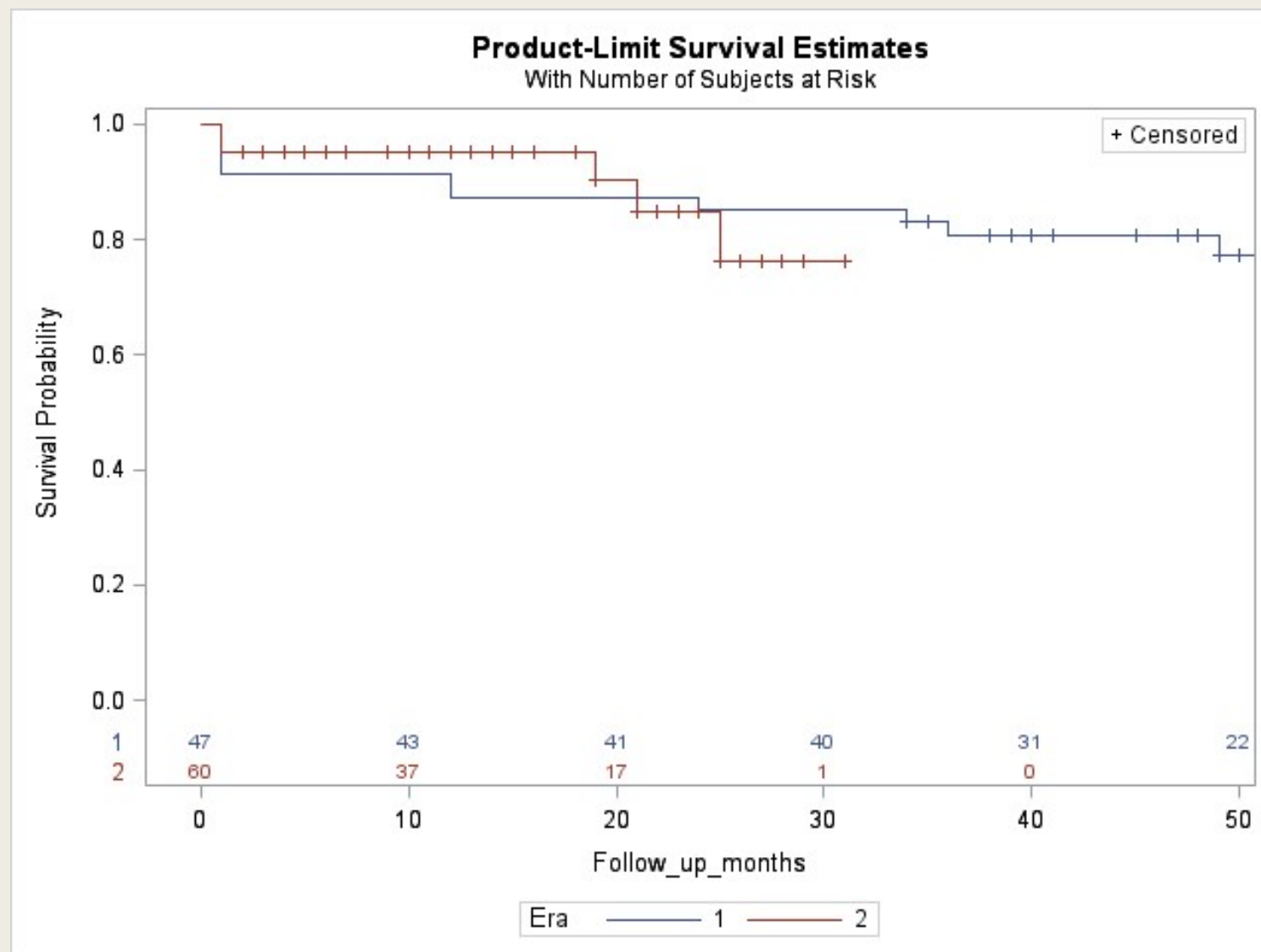
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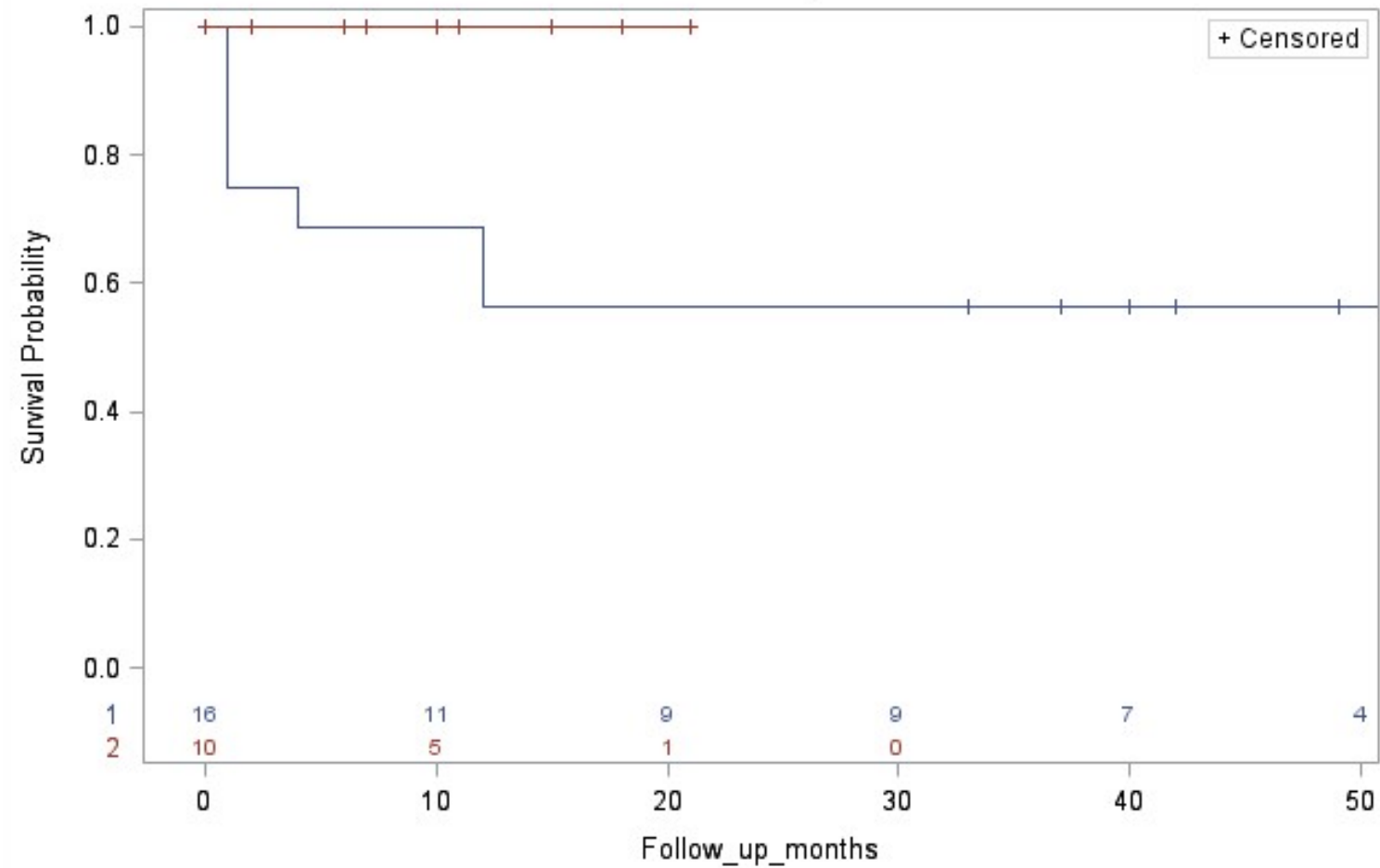
Inside IFU

- The following significant differences between the two eras were found: Era 2 was characterised by
  - *A higher proportion of female patients (22% vs. 6%).*
  - *A higher proportion of patients with respiratory risks (62% vs. 28%).*
  - *A higher prevalence of symptomatic cases (22% vs. 6%).*
  - *A lower proportion of scallops (0% vs. 13%).*
  - *Longer median delay from plan to procedure (84 vs. 65 days)*
  - *Lower success rate for coeliac stents (77% vs. 97%).*
  - *Lower complication rate - adjunctive/additional stenting (0% vs. 13%).*

Type of pathology and extent of disease

- Combination of both aneurysms and dissection

  - *Most aneurysms were degenerative*

  - *3 aneurysms related to HIV.*

- Most dissections were secondary to hypertension

  - *3 patients who were known to have connective tissue disorders (Marfan Syndrome).*

HIV aneurysm patients have had excellent outcomes in terms of technical success and long term follow up

After December 2020

	1ˢᵗ 63 = 64 months			Next 68 = 30 months		
	Overall	Outside IFU (16)	Inside IFU (47)	Overall	Outside IFU (9)	Inside IFU (59)
Technical success		74%	98%		94.4%	96.8%
Peri-op mortality (n)	8 (13%)	4 (25%)	4 (9%)	3 (4.4%)	0 (0%)	3 (5%)