

Sex-based Analysis of Clinical Outcomes With The Use of Paclitaxel-coated Endovascular Therapies in the VQI Registry

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Introduction

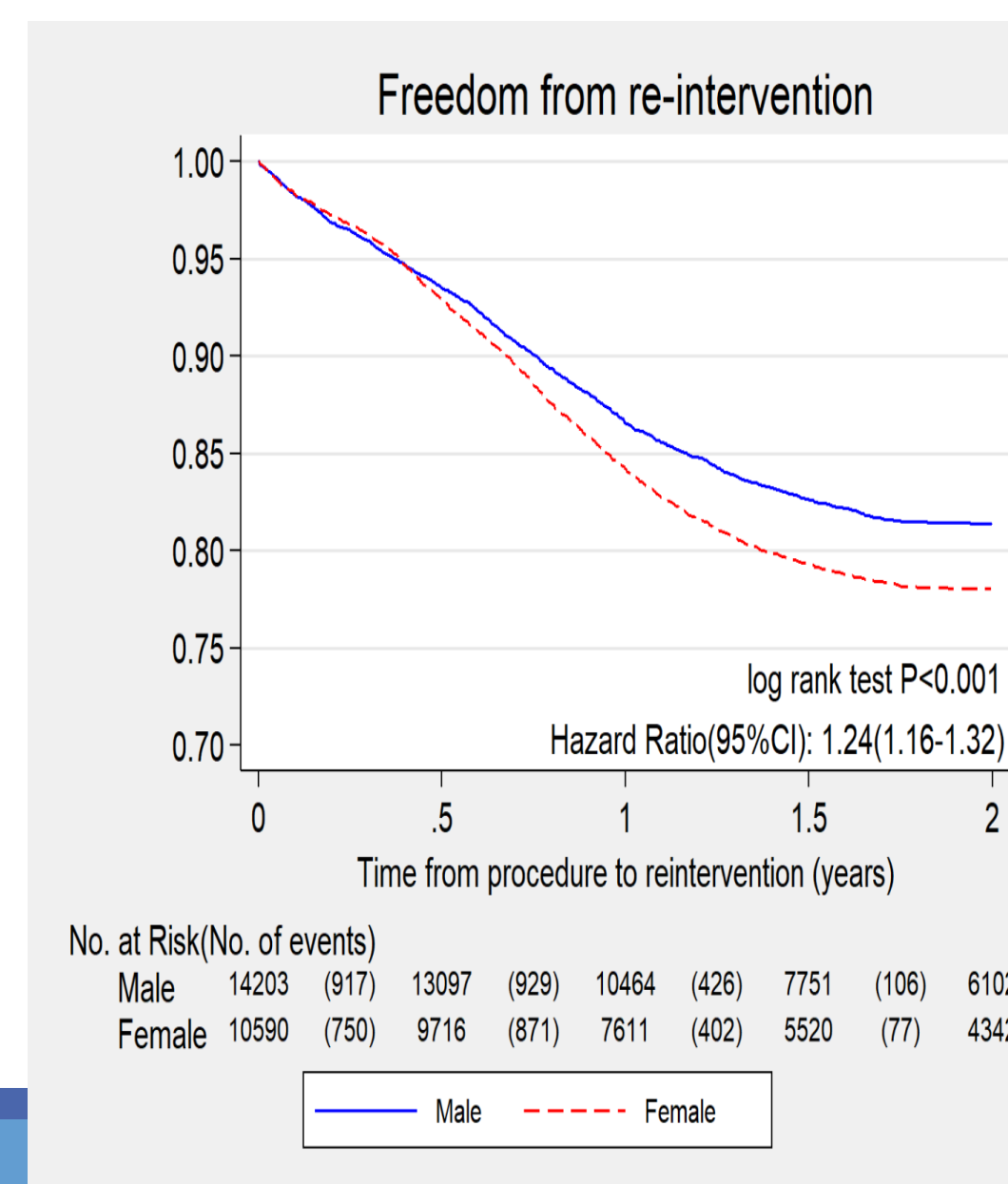
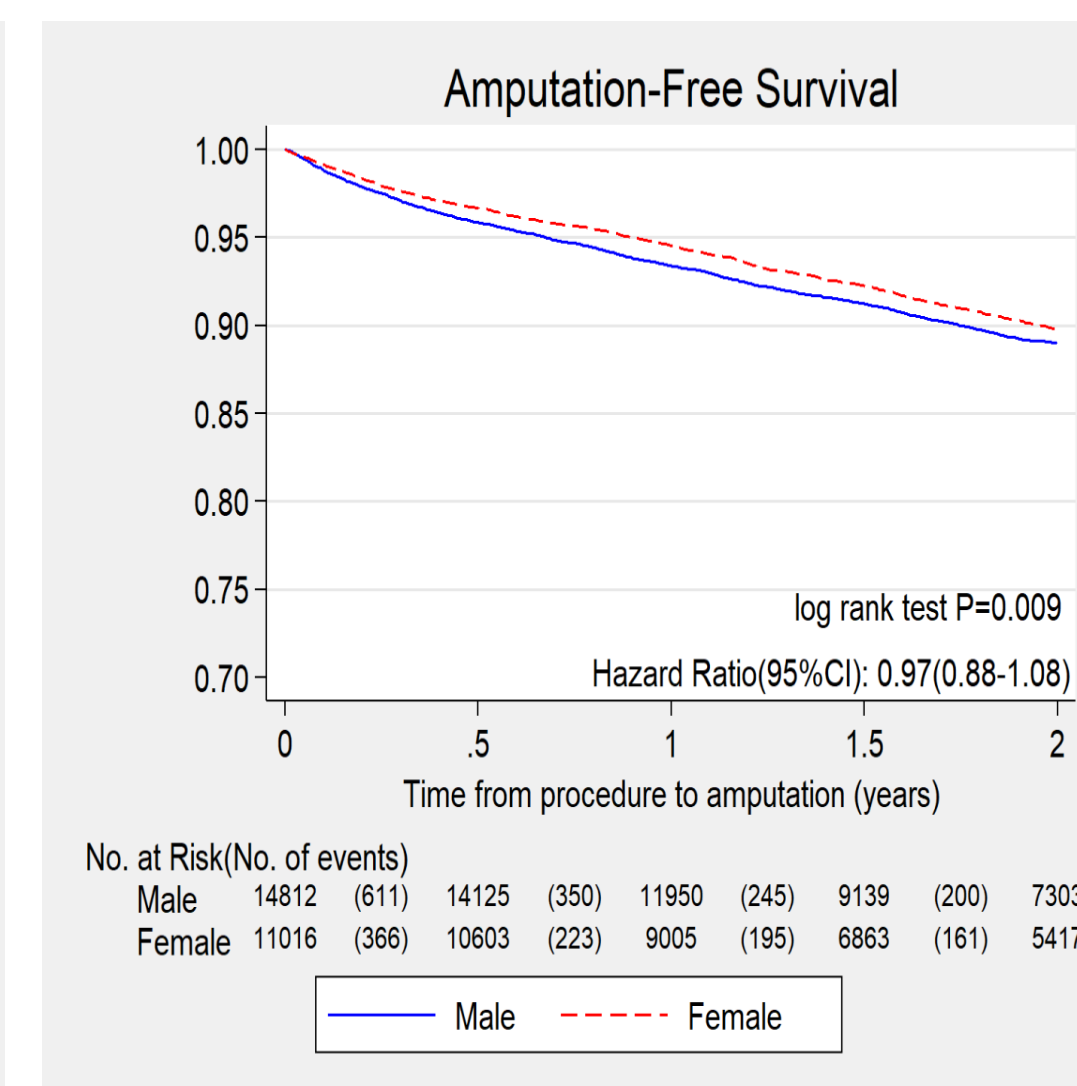
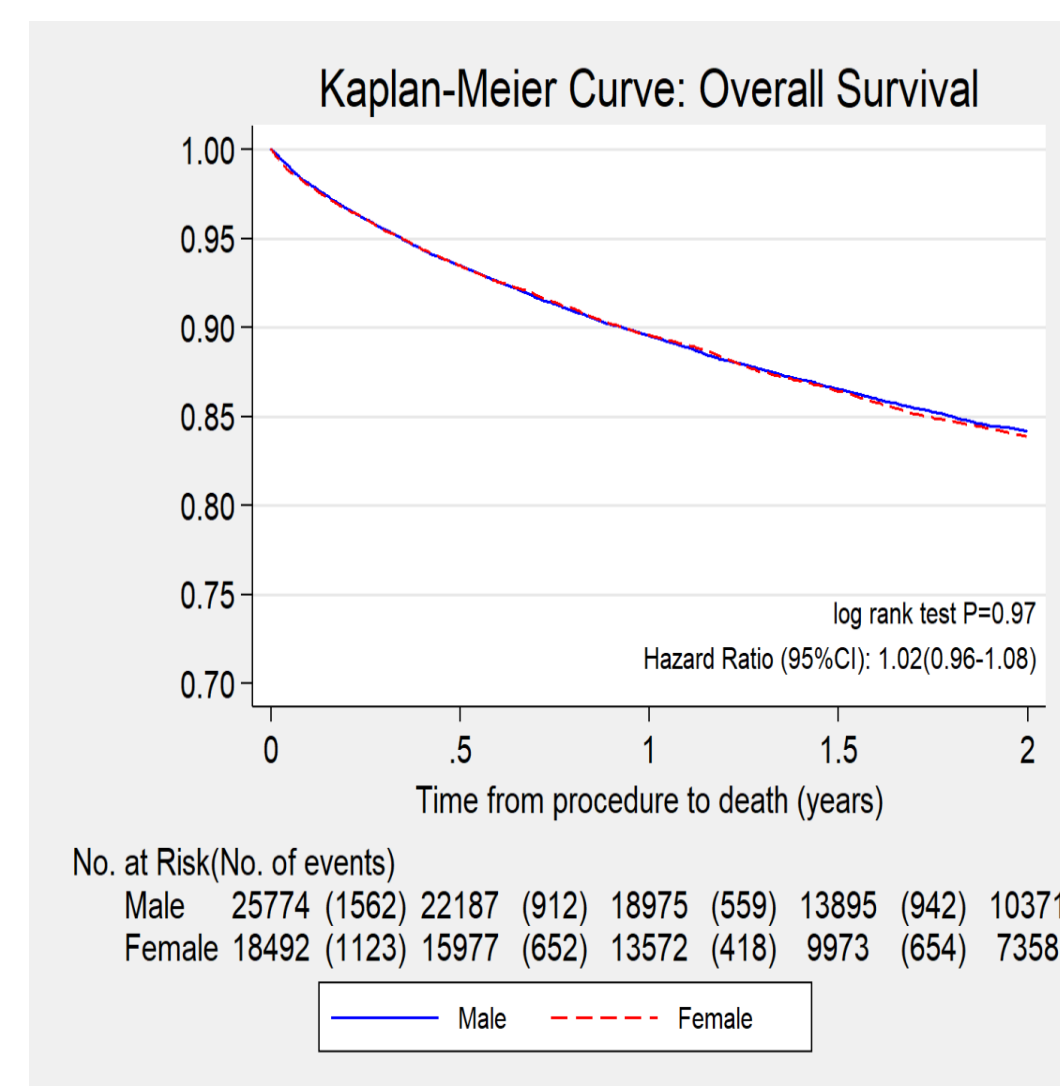
- Paclitaxel coated devices (PCD) whether balloons or stents are important tools for management of peripheral arterial disease.
- The concern over increased late mortality with use of PCD had been negated by extensive patient-level data.
- Limited research suggested sex-based differences in clinical outcomes, with the use of PCD favoring females.
- We aimed in this study to examine the sex-based differences in outcomes of PCD in a nationally representative database.

Methods

- Vascular Quality Initiative Peripheral Vascular Intervention (VQI-PVI) module from 2010 to 2022 who received PCD.
- We excluded patients undergoing concomitant bypass or have aneurysmal disease.
- Primary outcomes were 30-day and 2-year mortality, re-intervention, and ipsilateral major amputation.
- Logistic regression analysis was performed for 30-day outcomes. Survival analyses, Kaplan-Meier curves and proportional hazard Cox analyses were used to investigate the 2-year outcomes.

Results

Variables	Males 28,269 (58.3%)	Females 20,246 (41.7%)	p-value
Age>70	45.6%	51.6%	<.0001
Non-white race	19.6%	25.7%	<.0001
Hispanic	6.1%	7.3%	<.0001
Obese	31.8%	35.3%	<.0001
Hx of Stroke	15.6%	17.1%	<.0001
Mean creatinine (SD)	1.16 (0.57)	1.00 (0.53)	<.0001
CAD	40.6%	32.6%	<.0001
CHF	22.6%	21.6%	0.006
Smoking	85.4%	72.9%	<.0001
COPD	19.5%	23.3%	<.0001
DM	52.7%	50.7%	<.0001
Hx of prior bypass/PVI	58.0%	58.0%	0.988
Prior amputation	19.0%	14.9%	<.0001
Non-elective use	15.6%	15.8%	0.616
Preop ASA	73.9%	71.6%	<.0001
Preop P2Y12	49.9%	50.1%	0.585
Preop Statin	80.1%	74.8%	<.0001
Preop AC	21.5%	19.9%	<.0001
Preop Pletal	7.4%	6.8%	0.011
Fluorotime, min	21.48 (25.78)	19.29 (18.04)	<.0001
Contrast, ml	96.33 (61.92)	92.21 (59.48)	<.0001
Level of intervention:			<.0001
• Non-infrapopliteal	70.8%	74.5%	
• Infrapopliteal	29.2%	25.5%	
Treatment type:			<.0001
• Drug-coated balloon	80.2%	82.9%	
• Drug-eluting stent	19.8%	17.1%	
Discharged on ASA	80.0%	78.2%	<.0001
Discharged on P2Y	83.1%	82.6%	0.176
Discharged on DAPT	66.3%	64.4%	<.0001
Discharged on AC	25.3%	23.8%	<.0001
Discharged on Statin	86.1%	80.9%	<.0001



Conclusions

- There is no sex-based survival difference in patients receiving paclitaxel coated balloons or stents in the VQI.
- Females had higher risks of reintervention with slightly greater limb preservation.
- The 2-year hazard of re-intervention was 24% higher in females compared to males adjusting for level of disease, comorbidities, treatment type (balloon versus stent), prior intervention and medications at discharge.
- The unadjusted amputation-free survival was slightly better in females despite the higher re-intervention rates, but that difference dissipated with adjustment.