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Predictors of complications and extended length of stay following percutaneous transluminal renal artery angioplasty

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Abstract

Patients with renal artery stenosis (RAS) who fail medical management may be evaluated for Percutaneous transluminal renal artery angioplasty/stenting (PTRA/S). Comorbidities increasing the risk of complications following PTRA have not been explored well. Patients undergoing PTRA/S for RAS were sampled using National Inpatient Sample (NIS) Database. Demographics, length of stay (LOS), and comorbidities were gathered using ICD-10 codes. Complications included heart failure, myocardial infarction, cardiac arrest, major bleeding, stent thrombosis, renal artery dissection/embolism, aortic dissection/rupture and atheroembolism. Extended length of stay (ELOS) was defined as LOS >4 days. Univariate and multivariate logistic regression analyses were used to identify predictors for complications and ELOS. A sum of 517 patients underwent PTRA. Most prevalent comorbidities were peripheral vascular disease, coronary artery disease and dyslipidemia. On multivariate analysis, comorbidities significant for predicting major complications were end-stage renal disease, chronic liver disease, heart failure and coagulable disorders whereas comorbidities significant for predicting ELOS were age, chronic obstructive pulmonary disease, chronic kidney disease, anemia, chronic heart failure, and coagulable disorders. As we continue to identify the ideal candidates for PTRA, it is important to consider the comorbidities that predispose these patients to increased periprocedural complications and ELOS.

Abbreviations: CAD = coronary artery disease, COPD = chronic obstructive pulmonary disease, DM = diabetes mellitus, ELOS = extended length of hospital stay, ESRD = end-stage renal disease, PTRA/S = percutaneous renal artery angioplasty/stenting, RAS = renal artery stenosis.

Keywords: percutaneous transluminal renal artery angioplasty, renal artery stenosis, periprocedural complications, length of stay

1. Introduction

Renal artery stenosis (RAS) is a highly prevalent hypertensive disease that affects renal blood flow. For patients over 50 years old, the prevalence is 10% to 15% and can rise to 50% to 60% in older patients with atherosclerotic coronary or peripheral vascular disease, and kidney dysfunction.[1] The vast majority (around 90%) of RAS is secondary to atherosclerosis, while other etiologies include fibromuscular dysplasia and vasculitis. Atherosclerotic RAS is a progressive disease and is associated with severe comorbidities.[2] In the United States, 12% to 14% of dialysis-dependent patients have atherosclerotic RAS. Additionally, RAS can also present as various hypertensive syndromes such as resistant hypertension or new-onset severe hypertension with cardiovascular destabilization.[1]

While RAS can be treated using conservative medical therapy and lifestyle modifications, patients who do not respond to these measures may require procedural intervention, such as percutaneous renal artery angioplasty/stenting (PTRA/S).[3] PTRA/S has become the preferred invasive technique in recent times because it is less invasive and has lower associated morbidity when compared to surgical revascularization.[4,5] However, selecting the ideal patient candidate for elective PTRA/S to achieve optimal patient outcomes is still a topic of debate and needs further high-powered and optimally designed trials.

AM and CW contributed to this article equally.

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The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.

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The postoperative complications of PTRA/S may include venous thromboembolisms, bleeding, renal artery infarction, and need for hemodialysis.[6] However, comorbidities that may increase the probability of postoperative cardiovascular complications in patients undergoing PTRA/S are not well studied.[6] Acute complications after angioplasty or stenting can prolong hospital stay leading to increased utilization of hospital resources and healthcare costs.[7] The predictors for an increased length of hospital stay after PTRA/S are also not well defined. For interventionalists, understanding the postoperative risk due to baseline comorbidities will result in decreasing postoperative complications and preventing extended length of hospital stay (ELOS).

The aim of this study is to evaluate the baseline comorbidities that increase the risk for postoperative cardiovascular complications and ELOS following PTRA/S using a retrospective national database.

2. Materials and methods

Patients that underwent elective PTRA/S for RAS were sampled from the 2016 to 2018 National Inpatient Sample (NIS) database. The NIS database is the largest inpatient database in the United States funded through the Healthcare Cost and Utilization Project (HCUP).[8] This database contains de-identified data and IRB review was exempted as per HCUP data use agreement.

Demographics, mortality, and length of hospital stay (LOS) were collected from the database. Baseline patient comorbidities and cardiovascular complications were collected using International Classification of Disease 10 (ICD-10) codes (Table S1, Supplemental Digital Content, http://links.lww.com/MD/O241).

The comorbidities included in the study were selected based on prior studies evaluating post-procedural complications following cardiovascular interventions.[9] These factors have been used to predict mortality and length of stay. They include age, gender, diabetes mellitus, chronic kidney disease (CKD) stages 3 to 5, end-stage renal disease (ESRD), chronic obstructive pulmonary disease (COPD), smoking, carotid artery disease, valvular disorders, anemia, chronic liver disease, cardiovascular implantable electronic devices (CIED), atrial fibrillation, coronary artery disease, dyslipidemia, pulmonary circulatory disorders, cancer, coagulable disorders, and peripheral vascular disease.

Postoperative cardiovascular and procedural complications were divided into major and minor complications. Major complications included, ST elevated myocardial infarction (STEMI), acute heart failure, cardiac arrest, retroperitoneal hematoma, postprocedural anemia requiring packed red blood cell transfusion, stent thrombosis, renal artery embolism/kidney infarction, renal artery dissection, and abdominal aortic dissection/rupture. Minor complications included periprocedural bleeding/hematoma and postprocedural anemia not requiring blood transfusion. The primary endpoint was a composite of mortality and major complications. An ELOS was defined as a LOS >5 days (25th–75th percentile: 2–9 days) based upon the median length of stay for an elective PTRA/S in the NIS database. Cost was calculated by multiplying the total cost charge by the cost-charge ratio (CCR) and adjusted for USA annual inflation.

Statistical analysis was performed using Statistical Package for Social Sciences (IBM SPSS, Version 28, Armonk). Univariate analyses with chi-square and Student *t*-test analyses were utilized to identify predictors (demographics and comorbidities) for primary endpoint, as well as for major and minor complications, and extended LOS. Factors with $P < .20$ on univariate analyses were included for multivariate analyses. Multivariate analyses utilizing binary logistic regression were performed to evaluate independent risk factors for significant postoperative outcomes. *P* values <.05 were deemed statistically significant.

3. Results

A sum of 517 patients underwent elective PTRA/S. Over 50% of patients were female and the mean age was 71.1 years old. The top 5 most prevalent comorbidities were peripheral vascular disease (69.2%), coronary artery disease (CAD; 48.9%), dyslipidemia (43.9%), diabetes mellitus (DM; 28.2%), and COPD (26.7%; Table 1). The median healthcare cost per patient was 26,299$.

The most common complication was postprocedural anemia (14.3%), but none required perioperative packed red blood cell transfusion. Amongst major complications, the most common was acute periprocedural heart failure and occurred in 6% of the patients. None of the patients had periprocedural cardiac arrest, renal artery stent thrombosis, or atheroembolism. The primary endpoint occurred in 65 patients (12.6%) and 140 patients had an ELOS (27.1%; Table 2).

Comorbidities that were significant for predicting primary endpoint included ESRD, COPD, valvular disorder, chronic liver disease, chronic heart failure, CAD, dyslipidemia, and coagulable disorders (Table 3). After adjusting for confounders using multivariate logistic regression analysis, ESRD (adjusted-OR: 3.41 [1.07–10.84]; $P = .04$), chronic liver disease (adjusted OR: 9.2 [1.7–48.2]; $P = .01$), chronic heart failure (adjusted OR: 3.29 [1.76–6.16]; $P < .001$), and coagulable disorders (adjusted OR: 3.14 [1.41–7.00]; $P = .005$) were independently associated for the primary endpoint following elective PTRA/S (Table 4).

The median LOS was 5 days (2–9 days; Fig. 1). Comorbidities that were significant for predicting ELOS in univariate analyses included diabetes, COPD, valvular disorders, anemia, chronic liver disease, chronic heart failure, dyslipidemia, coagulable disorders, and age (Table 5). After adjusting for confounders using multivariate analysis, age (adjusted-OR: 0.98 [0.05–0.99]; $P = .004$), CKD (adjusted-OR: 2.06 [1.11–3.67]; $P = .02$), COPD (adjusted-OR: 2.43 [1.57–4.43]; $P < .001$), anemia (adjusted-OR: 3.8 [1.97–6.55]; $P \leq 0.001$), chronic heart failure (adjusted-OR: 1.52 [1.04–3.39]; $P = .04$), and coagulable disorders (adjusted-OR: 10.0 [6.2–31.0]; $P < .001$) were comorbidities that were independently associated with a LOS >5 days following elective PTRA/S (Table 6; Fig. 2).

Table 1

Baseline characteristics. Values are either mean ± SD or N (%). Healthcare cost is represented as median with 25th and 75th percentile.

Baseline characteristics	N = 517
Age	71.1 ± 11.1
Female	261 (50.5)
Diabetes mellitus	146 (28.2)
Chronic kidney disease 3–5	96 (18.6)
End-stage renal disease	21 (4.1)
Chronic obstructive pulmonary disease	138 (26.7)
Smoking	65 (12.6)
Carotid artery disease	11 (2.1)
Valvular disorders	51 (9.9)
Anemia	81 (15.7)
Chronic liver disease	8 (1.5)
Heart failure	100 (19.3)
Obesity	61 (11.8)
Cardiovascular implantable electronic device	24 (4.6)
Atrial fibrillation	20 (3.9)
Coronary artery disease	253 (48.9)
Dyslipidemia	227 (43.9)
Pulmonary circulatory disorders	17 (3.3)
Cancer	11 (2.1)
Coagulable disorders	40 (7.7)
Peripheral vascular disease	358 (69.2)
Healthcare cost ($)	26,299 (14,884–42,742)

4. Discussion

Data on periprocedural cardiovascular complications from large cohorts following elective PTRA/S is lacking. Our study retrospectively identified co-morbidities that were independently associated with major periprocedural cardiovascular complication following elective PTRA/S. We also identified the comorbidities that were associated with an ELOS. The independent predictors for primary endpoint were ESRD, chronic liver disease, chronic heart failure, and coagulable disorders. The independent factors associated with ELOS were age, chronic kidney disease, COPD, anemia, chronic heart failure, and coagulable disorders.

Although the cardiovascular outcomes in renal atherosclerotic lesions (CORAL), ASTRAL and RADAR trials did not show a statistically significant benefit of PTRA/S as compared to best medical therapy, certain limitations of these trials must be acknowledged.[10–12] Patients who would likely have benefited from intervention, such as those with severe stenosis and resistant hypertension, were often excluded. The RADAR trial was prematurely terminated because of poor patient recruitment, enrolling only 86 out of the 300 intended patients.[13] Furthermore, 25% of the patients included in the ASTRAL trial had normal renal function and many of the hypertensive patients included in the trial did not meet criteria for resistant hypertension, as they were on an average of 2.8 anti-hypertensive medications and had blood pressure readings that averaged around 150/75 mm Hg. In addition, 41% of the patients enrolled in the trial had only mild to moderate RAS (70% or less).[14] The HERCULES trial, through proper patient selection demonstrated a statistically significant reduction in both systolic and diastolic blood pressures.[15] Patients enrolled in the HERCULES trial were more severely hypertensive and were taking more medications when compared to the subjects enrolled in the CORAL trial.[15] There have been multiple single-center, prospective or retrospective studies that demonstrate beneficial outcomes in the intervention cohorts. A study including 500 patients with resistant hypertension due to RAS showed that surgical revascularization was effective treatment for hypertension in more than 75% of the patients.[16] The information presented highlights the importance of choosing the appropriate patients for PTRA/S to maximize benefits.

However, PTRA/S has not reliably shown to improve renal function and blood pressure in patients with advanced kidney dysfunction.[17] One study of 118 patients with RAS and moderate to severe chronic kidney disease, reported PTRA/S and medical therapy having comparable results in stabilizing renal function.[18] Another study evaluating outcomes of PTRA/S in patients with varying degree of renal failure reported that advanced renal dysfunction (creatine level of > 300 µmol/L) was associated with a lower survival rate.[19] Additionally, a combination of congestive heart failure and preoperative renal insufficiency have also been significantly associated with mortality during the follow-up period.[16] Patients with renal insufficiency have increased risk of bleeding complications.[20] Due to the higher rates of complications and minimal benefits, we advise against using PTRA/S in patients with ESRD.

Table 2

Total procedural complications. Values are either N (%).

Complication type	N = 517
All-cause mortality	13 (2.5)
Major complications	
ST-elevation myocardial infarction	1 (0.2)
Periprocedural acute heart failure	31 (6.0)
Periprocedural cardiac arrest	0 (0)
Retroperitoneal hematoma	6 (1.2)
Postprocedural anemia requiring packed red blood cell transfusion	0 (0)
Renal artery stent thrombosis	0 (0)
Renal artery embolism/kidney infarction	5 (1)
Renal artery dissection	6 (1.2)
Abdominal aortic dissection or rupture	6 (1.2)
Atheroembolism	0 (0)
Minor complications	
Periprocedural bleeding/hematoma	14 (2.7)
Postprocedural anemia	74 (14.3)
Primary endpoint (includes major cardiovascular complication and mortality)	65 (12.6)
Extended length of stay (LOS > 5 days)	406 (78.5)

LOS = length of stay.

Table 3

Major procedural complications. Values are either mean ± SD or N (%). Healthcare cost is represented as median with 25th and 75th percentile.

	Primary endpoint (N = 65)	Others (N = 452)	*P* value
Age	71.3 ± 10.4	71.1 ± 11.1	.91
Female	34 (52.3)	227 (50.2)	.75
Diabetes mellitus	25 (38.5)	121 (26.8)	.05
Chronic kidney disease 3–5	14 (21.5)	82 (18.1)	.51
End-stage renal disease	6 (9.2)	15 (3.3)	**.04**
Chronic obstructive pulmonary disease	25 (38.5)	113 (25.0)	**.02**
Smoking	25 (12.6)	40 (12.6)	.996
Carotid artery disease	1 (1.5)	10 (2.2)	1.00
Valvular disorders	11 (16.9)	40 (8.8)	**.04**
Anemia	14 (21.5)	67 (14.8)	.16
Chronic liver disease	4 (6.2)	4 (0.9)	**.01**
Heart failure	28 (43.1)	72 (15.9)	**<.001**
Obesity	4 (6.2)	57 (12.6)	.13
Cardiovascular implantable electronic device	4 (6.2)	20 (4.4)	.53
Atrial fibrillation	2 (3.1)	18 (4.0)	1.00
Coronary artery disease	43 (66.2)	210 (46.5)	**.003**
Dyslipidemia	40 (61.5)	187 (41.4)	**.002**
Pulmonary circulatory disorders	5 (7.7)	12 (2.7)	.05
Cancer	0 (0.0)	11 (2.4)	.37
Coagulable disorders	12 (18.5)	28 (6.2)	**<.001**
Peripheral vascular disease	46 (70.8)	312 (69.0)	.78
Healthcare cost ($)	35,936 (23,052–78,972)	24,428 (14,121–40,007)	**<.001**

Table 4

Multivariate logistic regression analysis of primary endpoint.

Primary endpoint				
	Adjusted OR	**Lower 95% CI**	**Upper 95% CI**	***P* value**
Diabetes mellitus	1.33	0.72	2.44	.37
End-stage renal disease	3.41	1.07	10.84	**.04**
Chronic obstructive pulmonary disease	1.79	0.98	3.27	.06
Valvular disorders	1.38	0.58	3.30	.47
Anemia	1.02	0.48	2.16	.96
Chronic liver disease	9.15	1.74	48.21	**.01**
Chronic heart failure	3.29	1.76	6.16	**<.001**
Obesity	2.41	0.77	7.55	.13
Coronary artery disease	1.60	0.88	2.93	.126
Dyslipidemia	1.75	0.97	3.15	.06
Pulmonary circulatory disorders	1.52	0.44	5.28	.51
Coagulable disorders	3.14	1.41	7.00	**.005**

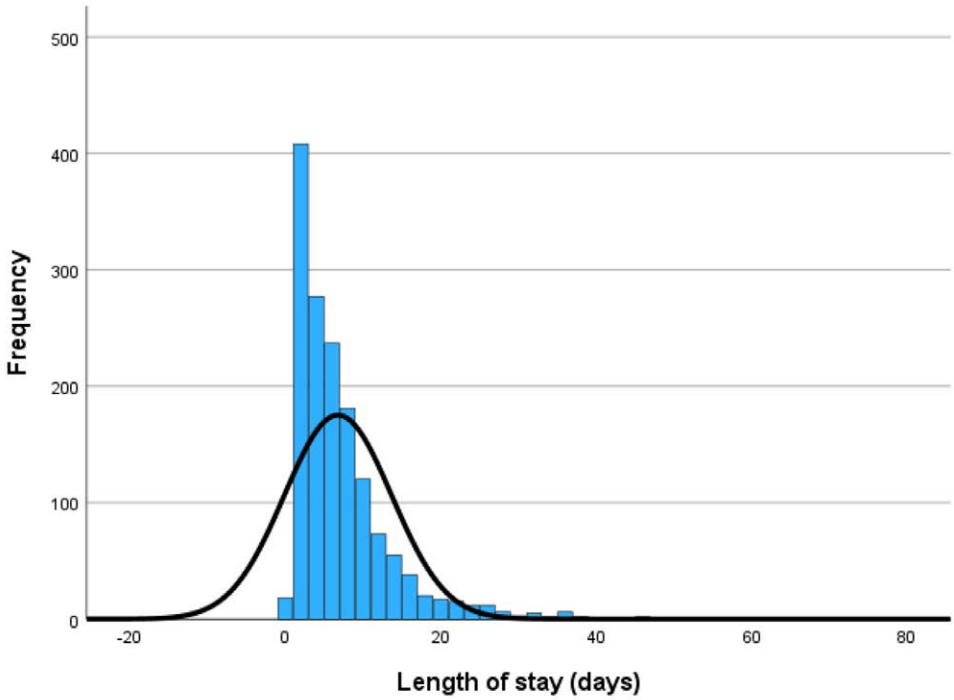

Figure 1. Histogram of length of hospital stay in elective PTRA/s. PTRA/S = percutaneous transluminal renal artery angioplasty.

RAS is often associated with other comorbid conditions that contribute to higher cardiovascular complications and mortality.[21] For example, bilateral RAS is more prevalent in diabetic patients.[22] Liver dysfunction, identified as an independent predictor for both complications and ELOS following PTRA/S, has previously been reported to be associated with poor outcomes in patients undergoing various cardiovascular procedures.[23–25] Chronic liver dysfunction was associated with increased hospital cost and length of stay following cardiac surgery.[24] As Child–Turcotte–Pugh class increased from A to C, mortality rate increased from 9% to 48%.[23] The likely underlying mechanism is the coagulopathy associated with liver dysfunction. Microvascular dysfunction was found to be 4 times as likely in patients with hypercoagulability undergoing percutaneous coronary intervention, hence contributing to thromboembolic microvascular obstruction.[26] In patients following coronary artery bypass grafting, hypercoagulability was associated with increased 30-day postoperative events, specifically acute myocardial infarction, stroke, and mortality.[27] Chronic heart failure patients are also prone to cardiovascular complications following vascular procedures.[28] Patients with chronic heart failure had increased long-term mortality following PTRA/S.[29] In other vascular procedures, especially major procedures, heart failure and DM were significantly associated with cardiac-related mortality.[30]

The study highlights the importance of preoperative optimization of patients undergoing PTRA/S to reduce complications and ELOS. Furthermore, both the primary endpoint and ELOS were associated with a significant increase in healthcare cost by at least $10,000. Given that 12.6% of patients that underwent PTRA/S developed major cardiovascular complications, special attention should be given to patients with chronic kidney disease, anemia, congestive heart failure and coagulable disorders. Patients with chronic liver disease can be optimized preoperatively by correcting coagulopathy, improving nutritional status, and treating associated conditions such as hepatic encephalopathy.[31] The MELD score has been proven as a reliable tool for predicting postoperative morbidity and mortality of both hepatic and non-hepatic surgery in patients with chronic liver disease.[32] While the benefits of PTRA/S in ESRD patients are still a topic of debate, preoperative optimization for those selected for the procedure should

Table 5

Baseline comorbidities for extended length of stay (ELOS). Values are either mean ± SD or N (%). Healthcare cost is represented as median with 25th and 75th percentile.

	Extended LOS (>5 days) N = 406	Optimal LOS (≤5 days) N = 111	*P* value
Age	69.4 (13.3)	71.8 (10.0)	**.03**
Gender (female)	198 (48.8)	63 (56.8)	.14
Diabetes mellitus	105 (25.9)	41 (36.9)	**.02**
Chronic kidney disease 3–5	70 (17.2)	26 (23.4)	.14
End-stage renal disease	13 (3.2)	8 (7.2)	.10
Chronic obstructive pulmonary disease	92 (22.7)	46 (41.4)	**<.001**
Smoking	151 (37.2)	48 (32.2)	.25
Carotid artery disease	8 (2.0)	3 (2.7)	.71
Valvular disorders	34 (8.4)	17 (15.3)	**.03**
Anemia	44 (10.8)	37 (33.3)	**<.001**
Chronic liver disease	3 (0.7)	5 (4.5)	**.01**
Chronic heart failure	66 (16.3)	34 (30.6)	**<.001**
Obesity	46 (11.3)	15 (13.5)	.53
Cardiovascular implantable electronic device	16 (3.9)	8 (7.2)	.15
Atrial fibrillation	15 (3.7)	5 (4.5)	.78
Coronary artery disease	193 (47.5)	60 (54.1)	.22
Dyslipidemia	168 (41.4)	59 (53.2)	**.03**
Pulmonary circulatory disorders	10 (2.5)	7 (6.3)	.07
Cancer	8 (2.0)	3 (2.7)	.71
Coagulable disorders	13 (3.2)	27 (24.3)	**<.001**
Peripheral vascular disease	280 (69.0)	78 (70.3)	.79
Healthcare cost ($)	47,241 (30,653–71,579)	21,580 (13,170–36,608)	**<.001**

ELOS = extended length of stay, LOS = length of stay.

Table 6

Predictors of extended LOS on multivariate regression.

Extended length of stay (LOS > 5d)				
	Adjusted OR	Lower 95% CI	Upper 95% CI	*P* value
Age	0.98	0.95	0.99	**.004**
Gender (female)	1.23	0.63	1.72	.86
Chronic kidney disease 3–5	2.06	1.11	3.67	**.02**
End-stage renal disease	1.53	0.43	4.18	.61
Chronic obstructive pulmonary disease	2.43	1.57	4.43	**<.001**
Valvular disorders	1.89	0.71	3.42	.27
Anemia	3.75	1.97	6.55	**<.001**
Chronic liver disease	6.79	0.86	24.81	.08
Diabetes mellitus	1.64	0.91	2.65	.11
Chronic heart failure	1.52	1.04	3.39	**.04**
Cardiovascular implantable electronic device	1.35	0.50	3.66	.55
Dyslipidemia	1.05	0.82	2.23	.23
Pulmonary circulatory disorders	1.48	0.53	5.92	.35
Coagulable disorders	9.99	6.19	30.96	**<.001**

LOS = length of stay.

involve optimal timing of dialysis, achieving euvolemia, and correcting electrolyte abnormalities.[20,33] Preoperative optimization of patients with heart failure should include correction of possible underlying reversible causes of anemia. Optimization of guideline directed medical therapy before the procedure should be prioritized to prevent complications.[34–36]

Several limitations need to be mentioned in this study. This study is retrospective in nature and our findings may change over time. Our analyses utilized ICD-10 codes to identify comorbidities, which can be prone to coding error. Acute renal failure could not be assessed in our study as we were unable to determine whether these events occurred preoperatively or postoperatively. Thus, our study can be prone to selection bias. There can be unaccounted confounding variables present as our variables were identified using ICD-10 codes. Another limitation worth mentioning is the lack of detailed radiological and procedural data such as renal denervation, PTCA/balloon size, renal-to-aortic ratios, peak systolic velocity, degree of lesion, location, and length of stenosis. Despite these limitations, our study was able to overcome these biases as best as possible by utilizing multivariate logistic regression analysis.

This study not only shed light on predictors of postoperative cardiovascular outcomes and ELOS following PTRA/S, but also highlighted the paucity of data on the management of RAS. However, the available literature combined with our observation of ESRD, chronic liver disease, heart failure and coagulable disorders as independent predictors for major complications following PTRA/S will help interventionalist's in not only choosing the appropriate patients, but also help reduce postoperative complications through proper optimization of co-morbidities.

5. Conclusion

To our knowledge, this is the first study to evaluate postoperative cardiovascular complications in patients undergoing elective PTRA/S. Congestive heart failure, ESRD, coagulable disorders,

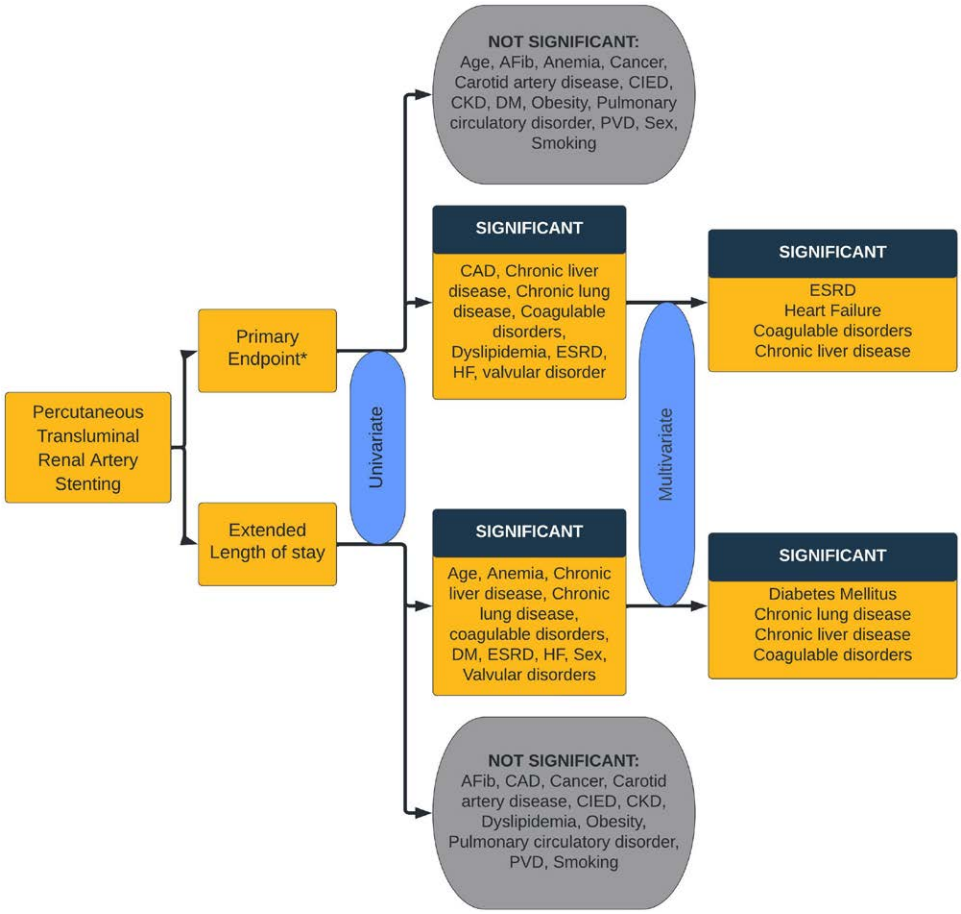

Figure 2. Central illustration. *Primary endpoint defined as a composite of major complications and mortality. Afib = atrial fibrillation, CAD = coronary artery disease, CIED = cardiovascular implantable electronic device, CKD = chronic kidney disease, DM = diabetes mellitus, ESRD = end-stage renal disease, HF = heart failure, PVD = peripheral vascular disease.

and chronic liver disease are associated with increased postoperative cardiovascular complications and an ELOS. Appropriate time and consideration should be given to optimization of above-mentioned co-morbidities prior to proceeding with PTRA/S to improve post-procedural outcomes and decrease healthcare costs.

Author contributions

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