A Cross-Sectional Imaging Study to Identify Organs at Risk of Thermal Injury During Renal Artery Sympathetic Denervation

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1. Introduction

Initial studies of renal artery sympathetic denervation as a treatment for resistant hypertension were so encouraging that they promoted investigators to launch studies to evaluate the role of this novel therapy in other conditions associated with sympathetic nervous system over activation [1-7]. For this reason, the results of the Symplicity HTN-3 trial surprised the cardiology community [8]. This trial reported that renal artery sympathetic denervation is ineffective at lowering blood pressure in patients with resistant hypertension when compared to a sham control group. Several hypotheses have been proposed to explain these disparate results [9-12]; one possibility is that the renal sympathetic nerves were inadequately ablated, perhaps due to operator or technological factors [13]. Supporting this hypothesis, a post-hoc analysis of Symplicity HTN-3 demonstrated that those patients who had received a more comprehensive ablation procedure, i.e. a larger number of ablations and therapy to all four quadrants of each renal artery, experienced a greater reduction in blood pressure [14].

Early adopters of renal denervation believed that the superior aspect of the renal artery ostium contained the greatest concentration of sympathetic nerves, and thus considered this a critical site for ablation [15]. This theory has since been dispelled by human histological data, which demonstrates that sympathetic nerves run in closer proximity to the distal rather than proximal renal artery, implying that ablation here may have a superior success rate [16]. This study also found that only 40% of renal sympathetic nerves are located within 2mm of the artery wall and it is unclear whether the first generation catheter has the capability to extend much beyond this. Newer catheters capable of creating a deeper ablation zone may target a greater proportion of sympathetic nerves and therefore be more effective [17].

Reflecting upon these new data, future trials of renal denervation may employ a more rigorous approach, with ablations being more numerous and more distally placed, including distal to bifurcations, and targeting all four quadrants of the artery [17, 18]. Furthermore, it may be desirable to create larger ablation zones [19]. The latest second generation catheters are designed to facilitate this strategy with: 1) multiple electrode configurations that allow uniform circumferential energy delivery (Spyral™, Vessix™, EnlighHTN™ and Paradise™) [15, 20]; 2) an ability to perform ablations in arteries as narrow as 3mm in diameter (Spyral™, Vessix™), thereby enabling more distal access compared to the previous limit of 4mm [21], and 3) deeper penetration into the renal adventitia (the Paradise™ system is able to create an ablation zone that extends 7-12mm from the renal artery wall) enabling attenuation of a greater proportion of the sympathetic nerves [22].

Whilst achieving adequate sympathetic nerve attenuation is clearly vital to the efficacy of the procedure, a balance must be struck with the potential risks that may be associated with an extensive ablation strategy that uses the measures outlined above [19, 23]. The purpose of this study is to explore one such risk - the potential for ‘comprehensive’ renal artery ablation to cause thermal injury to neighbouring structures. To this end, we reviewed a series of computerised tomograms (CTs) to identify those structures that lie in close proximity to the renal arteries, and which may be exposed to thermal energy using this contemporary approach.

2. Methods

2.1 Study Population

Two experienced radiologists independently reviewed consecutive CT aortograms, obtaining a total sample size of 100 kidneys considered anatomically eligible for renal denervation.

Demographic data and relevant past medical history were collected for each patient. National Health Service (UK) Management Permission for use of anonymised patient data for research was obtained, conforming to ethical standards [24].

2.2 Renal Artery Analysis

All images were acquired with a Siemens SOMATOM Definition Flash dual-source scanner, with a reconstructed slice thickness of 0.75mm [25]. Axial and coronal reconstructions were assessed for each patient thereby allowing adequate assessment of structures in both the antero-posterior and cranio-caudal axes. The arterial supply to each kidney was graded according to a modified classification [26], and the anatomic eligibility for renal denervation determined. Standard recommendations were adapted to use a renal artery diameter threshold of ≥3mm, rather than the conventional ≥4mm, thus encompassing the extended capability of some second-generation catheters. Renal arterial anatomy was categorised as follows: classically eligible (A), off-label eligible (B), or ineligible (C) (Figure 1).

Only renal arteries deemed eligible for denervation (classifications A or B) were included in the study. The '*at risk zone*' (ARZ) was defined as an area measuring 10mm (based on histology data from the Paradise™ system [22]) extending radially from the renal artery wall at any point between the ostium and the hilum, where the renal artery diameter was ≥3mm. Structures within the ARZ were documented, along with the shortest distance from the vessel wall at which these were found. In addition to this 10mm ARZ, structures within a smaller (5mm) zone were also evaluated to reflect the smaller ablation zones created by catheters with a lower maximum penetration. All measurements were rounded to the nearest mm. Any discrepancy in findings between the two observers was resolved by consensus.

2.3 Statistics

Continuous variables are presented as means with standard deviations (SD). Nominal variables are presented as counts and percentages or medians with 1st and 3rd quartiles. Fisher's exact test was used to compare categorical data. The McNemar test with the exact method was used to compare related categorical variables. All analyses were performed using SPSS (IBM version 22).

3. Results

Subjects had a mean age of 74.6 (SD 15.0) years and an average body mass index was 27.3 (SD 5.6). 24 (48%) were male, 44 (88%) had a history of hypertension and 41 (82%) had ischaemic heart disease.

Twenty-six of the 126 kidneys (63 patients) were ineligible; 18 due to renal artery stenosis, 4 due to a single renal artery that was either <3mm in diameter or <20mm in length with no branch being >3mm in diameter, and 4 due to multiple ineligible renal arteries.

Of the 100 eligible kidneys 73 were classically eligible for renal denervation and 27 were off-label eligible; of these, 7 had a side branch measuring ≥3mm in diameter within the first 20mm, 10 had multiple renal arteries each ≥3mm in diameter and ≥20mm in length prior to any bifurcation, and 10 had multiple renal arteries where at least one had a diameter ≥3mm and a length ≥20mm.

In 97% of kidneys, the renal veins lie within 10mm of the renal arteries, and the inferior vena cava (IVC) is always within the ARZ of the right renal artery (Figure 2 and 3). The psoas muscles (Figure 2) and small bowel (Figure 3) are found within the ARZ in a quarter of kidneys; however, this proportion is reduced when the smaller (5mm) zone is considered (Table 1). Neither large bowel nor renal parenchyma were found within the ARZ in any cases.

The IVC and liver (Figure 4) were only encountered within the ARZ on the right, whereas the pancreas (Figure 5), adrenal gland and splenic vasculature were more commonly encountered within the ARZ on the left (Table 1). In over 50% of kidneys the renal vein and/or IVC were within 1mm of the renal artery (Table 2).

Seventy-one kidneys were found to have arteries eligible for ablation before and after the first bifurcation; these are presented in Table 3. The IVC was more commonly found prior to the renal artery bifurcation whereas the psoas muscle, small bowel and liver were encountered more frequently distal to the first bifurcation (Table 3).

There was no significant difference in the frequency with which structures were encountered within the ARZ when comparing classically eligible (A) to off-label eligible (B) renal arteries, and no significant difference in the frequency with which structures occurred in the ARZ for smaller diameter arteries of 3-4mm when compared with classically accepted arteries measuring ≥4mm.

4. Discussion

We have found that in at least one-fifth of cases the renal vein, IVC, psoas muscle or small bowel are located within 10mm of the renal artery wall and thus may inadvertently receive thermal energy during a renal denervation procedure using the latest catheters.

Manufacturers of the commercially available ablation catheters used for renal sympathetic denervation tend not to openly disclose the exact size of the ablation zones that these create; this is surprising given the large number of patients in which this procedure has been performed worldwide. A literature review found only five reports that adequately described lesion dimensions [16]. Only one of these reports was in man and describes a single patient who died from an aortic dissection several days after receiving 11 ablations with the Symplicity™ catheter [27]; on post-mortem the maximum size of the ablation zone was 2mm. A study of catheter-based renal denervation in dogs using the EnligHTN™ system revealed that 90% of ablation zones did not extend beyond 3.5mm [28], and a recent study using the Symplicity™ catheter in swine found that mean distance to deepest thermal injury from the arterial lumen was 7.3mm [29]. Finally, a phantom gel model reported the mean size of ablation zones using Symplicity™ and EnligHTN™ catheters to be 3.8mm and 3.4mm respectively, although it is not possible to extrapolate the results of these studies to humans [30].

The Symplicity™ catheter has been used in the majority of trials and registries to date with no reports of abdominal organ damage; this suggests that either this risk is rare and largely theoretical or it is underreported presumably as the clinical consequences of inadvertent thermal injury to the structures commonly found in the ARZ are temporary. However, several different catheter systems have since been launched, each with varying electrode configuration, energy use and biophysical properties suggesting that a class effect for neither efficacy nor safety can be assumed [15, 31].

The only available ultrasound-based system for renal denervation (Paradise™) has been shown to have a maximum penetration depth of 7-12mm in swine [22]. The development of such powerful systems prompted us to elucidate which structures lie in the vicinity of renal arteries and thus may be affected by thermal energy. Given our findings, that in least one-fifth of eligible kidneys the renal vein, IVC, psoas muscle and small bowel are encountered within 10mm of the renal artery wall, it is interesting to note that in the animal study using the Paradise™ catheter there was evidence of small bowel necrosis and psoas muscle damage [22]. The authors of that study, based on unpublished industry data, suggested that these effects are less likely in humans due to anatomical differences between pigs and man. However, back or abdominal pain, the most commonly reported symptoms of psoas muscle and small bowel injury, have been described in up to 63% of patients following renal denervation [32]; we suggest that, if persistent, these symptoms should prompt further investigation.

Another option to optimise attenuation of renal sympathetic nerves is to exploit their non-uniform distribution. The nerves approximate the artery with increasing distance from the ostium (90% of sympathetic nerves are found within 9mm of the proximal main artery, 5mm of the distal main artery and 3mm of the post bifurcation artery) [16]. This implies that post-bifurcation vessels may be an attractive target for denervation, particularly as a 3mm ablation zone should be achievable by most catheters. In dogs, denervation of distal branch vessels (post bifurcation) resulted in a greater reduction in renal noradrenaline concentration (the key neurotransmitter of the sympathetic nervous system [33]) than when it was performed in the main vessel only [18]. Distal vessels will generally be smaller in calibre and with the advent of the next generation catheters the minimum renal artery diameter permitted for denervation has been reduced from 4mm to 3mm. Our data suggests that this change of practice would not increase the number or frequency with which structures are encountered in close vicinity to the vessel, i.e. within the ‘at risk zone’ where they may be exposed to thermal energy.

The biophysical principles of ablation determine the effect that thermal energy has on surrounding structures. Despite the close proximity of the IVC and the renal vein to the renal artery, the risk of damage to these is low since a high blood flow in these vessels will serve as a heat-sink [15]. The structures of greater concern are the solid organs such as bowel or liver, which do not have such protection. In our opinion, renal denervation should not be avoided in patients who on cross-sectional imaging have structures within the ARZ as currently any risk remains largely theoretical. However, we would suggest increased clinical vigilance peri-procedurally for complications within this cohort of patients.

4.1 Limitations

The subjects included in this study were not destined for renal denervation but instead underwent CT aortograms for other clinical indications. Patients receiving renal denervation tend to have resistant hypertension and it is conceivable with vascular remodelling that their anatomy may differ from age-matched controls. Interestingly though, a large renal angiography study showed there to be no significant difference in anatomy between those with resistant hypertension versus non-resistant hypertension [34], and 88% of our cohort were hypertensive. We also acknowledge the limitations of a retrospective study design, however, this should have no effect on an anatomical study.

5. Conclusions

Our study brings to our attention that at least one-fifth of renal arteries are in close proximity to vasculature, psoas muscle or small bowel, a finding that has not been previously reported. To date, safety has not been a significant consideration when using the first generation catheter. With the advent of more powerful catheters and a more comprehensive ablation strategy being preferred, the same safety profile cannot be assumed. The potential risk of psoas muscle or small bowel injury suggests a possible role for cross-sectional imaging prior to renal denervation to delineate individual anatomy at risk; as yet, however, the consequence of delivering thermal energy to these structures remains uncertain.

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Figure Legends

Figure 1: Classification of eligibility for renal denervation based on renal artery anatomy.

Figure 2: Axial computerised tomogram showing the close proximity of the right renal artery (white arrow), the right renal vein (RV) and the psoas muscles (PM).

Figure 3: Axial computerised tomogram showing the close proximity of the right renal artery (white arrow) and the inferior vena cava (IV) and the left renal artery (black arrow) and small bowel (SB).

Figure 4: Axial computerised tomogram showing the close proximity of the right renal artery (white arrow) and the liver (L).

Figure 5: Axial computerised tomogram showing the close proximity of the left renal artery (white arrow) and the pancreas (P).

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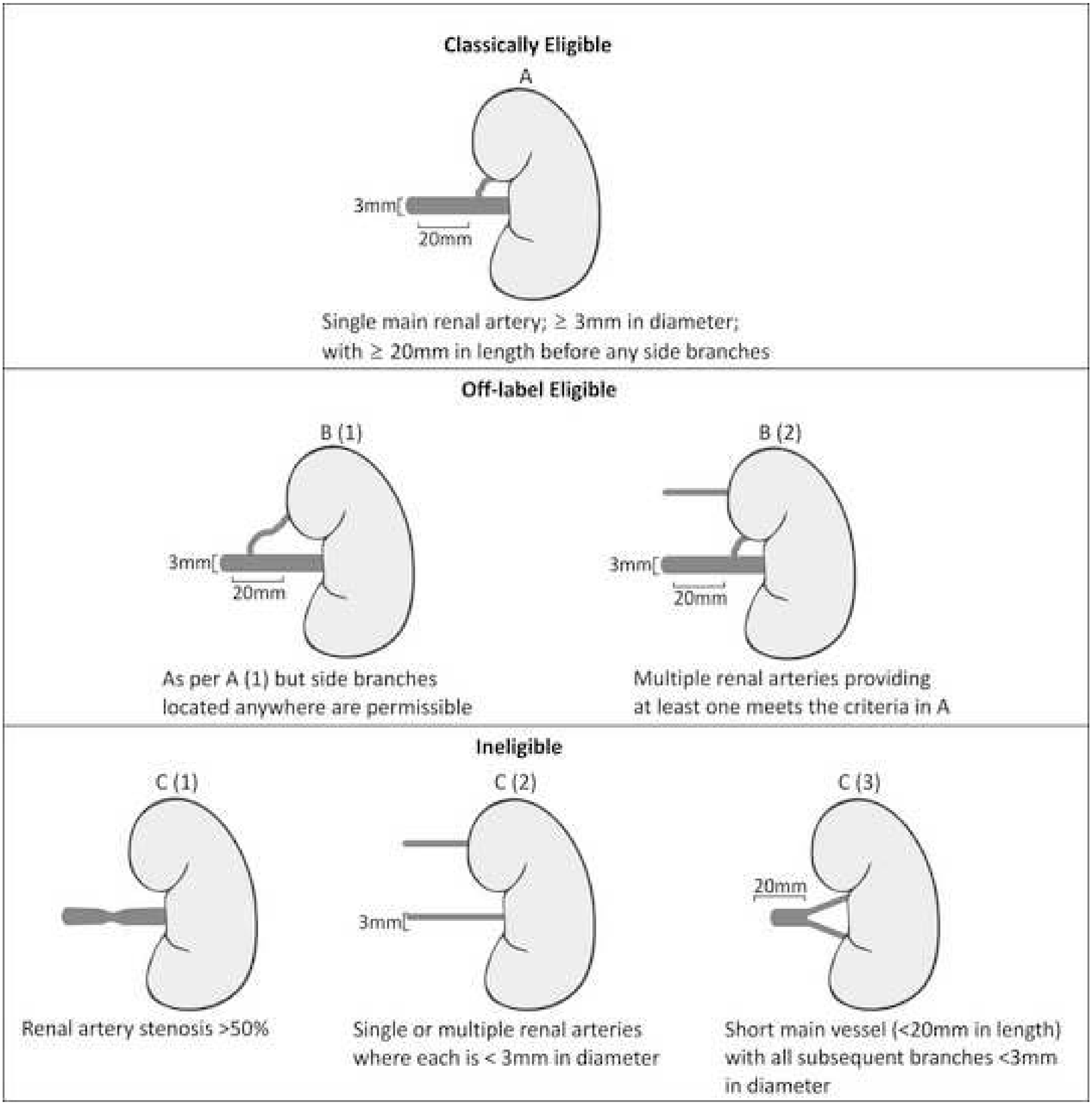
Figure 1



Single main renal artery; ≥ 3mm in diameter; with ≥ 20mm in length before any side branches

As per A (1) but side branches located anywhere are permissible

Multiple renal arteries providing at least one meets the criteria in A

Renal artery stenosis >50%

Single or multiple renal arteries where each is < 3mm in diameter

Short main vessel (<20mm in length) with all subsequent branches <3mm in diameter

Figure 2

Figure 3

Figure 4

Click here to download high resolution image

Figure 5

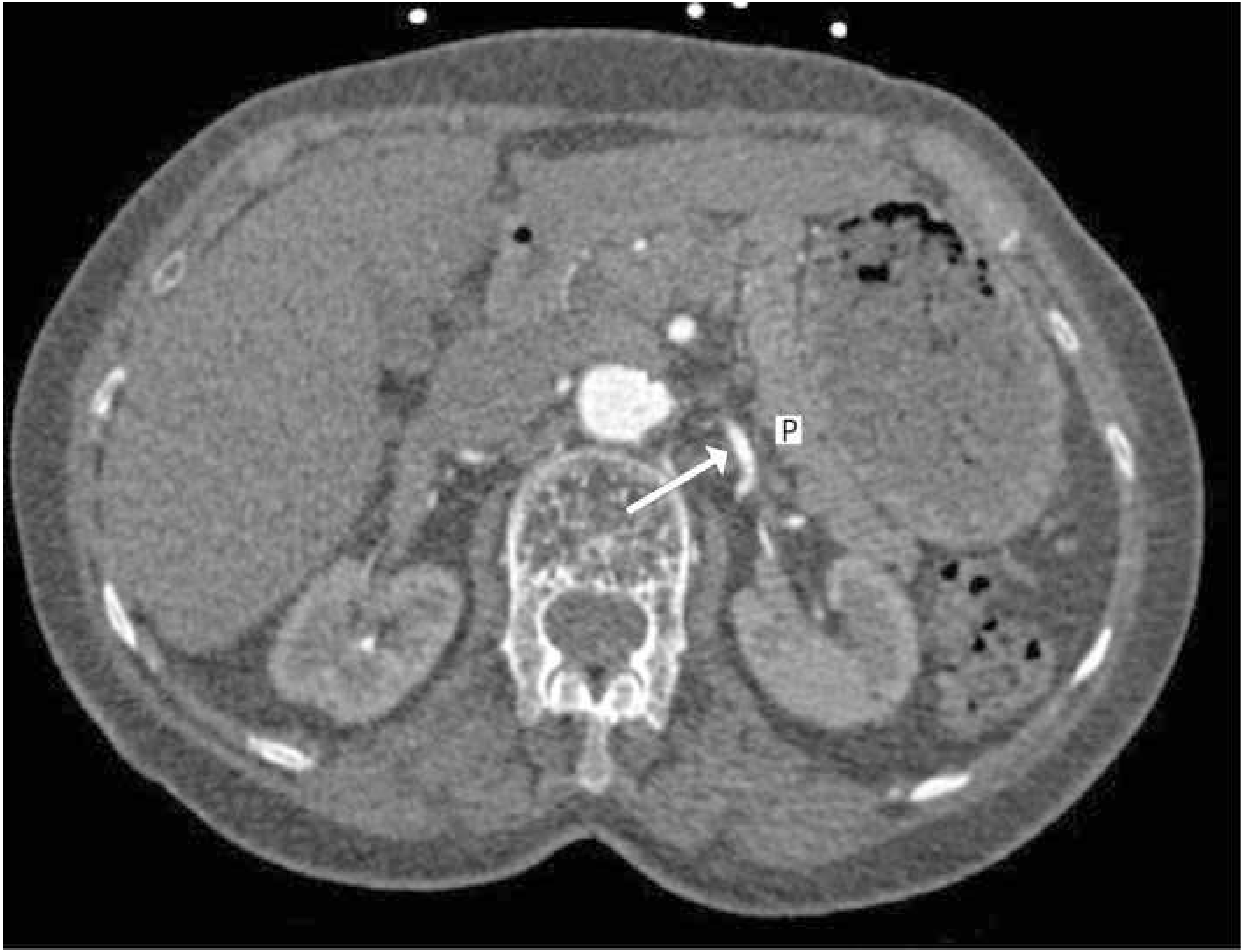


Table 1

Table 1: The frequency with which structures are encountered within 10mm and 5mm of the renal artery, comparing right with left.

Structures within 10 or 5mm of the renal artery	10mm				5mm				10mm vs 5mm
	Right Renal Artery (n=51)	Left Renal Artery (n=49)	Total (n=100)	R vs L P (Fisher's)	Right Renal Artery (n=51)	Left Renal Artery (n=49)	Total (n=100)	R vs L P (Fishers's)	P (McNemar's)
Renal Vein	50 (98%)	47 (96%)	97 (97%)	0.614	48 (94%)	42 (86%)	90 (90%)	0.196	0.016
IVC	51 (100%)	0 (0%)	51 (51%)	<0.001	51 (100%)	0 (0%)	51 (51%)	<0.001	1.000
Psoas Muscles	14 (28%)	11 (22%)	25 (25%)	0.647	10 (17%)	8 (16%)	18 (18%)	0.796	0.016
Small Bowel	13 (26%)	12 (25%)	25 (25%)	1.000	7 (14%)	4 (8%)	11 (11%)	0.526	<0.001
Pancreas	2 (4%)	8 (16%)	10 (10%)	0.049	1 (2%)	6 (12%)	7 (7%)	0.057	0.250
Liver	8 (16%)	0 (0%)	8 (8%)	0.006	3 (6%)	0 (0%)	3 (3%)	0.243	0.063
Adrenal	0 (0%)	7 (14%)	7 (7%)	0.005	0 (0%)	5 (10%)	5 (5%)	0.025	0.500
Diaphragm	3 (6%)	2 (4%)	5 (5%)	1.000	2 (4%)	1 (2%)	3 (3%)	1.000	0.500
Splenic Artery	0 (0%)	3 (6%)	3 (3%)	0.114	0 (0%)	2 (4%)	2 (2%)	0.238	0.500

Splenic Vein	0 (0%)	1 (2%)	1 (1%)	0.490	0 (0%)	0 (0%)	0 (0%)		0.500

Table 2: Median distance between structure and renal artery wall, quartile 1 (Q1), and quartile 3 (Q3).

	Median distance (Q1, Q3), mm
Renal Vein	1 (0, 2)
IVC	0 (0, 1)
Psoas Muscles	4 (3, 6)
Small Bowel	6 (3.5, 7)
Pancreas	5 (1, 6.3)
Liver	6.5 (4.3, 7.8)
Adrenal	3 (2, 6)
Diaphragm	4 (2.5, 9)
Splenic Artery	5 (3, 8)
Splenic Vein	7 (7,7)

Table 3

Table 3: Frequency with which structures are encountered within 10mm and 5mm of the renal artery wall before and after the first bifurcation. P values are from McNemar's test.

	10mm			**5mm**		
Structures	**Pre-Bifurcation (n=71)**	**Post-Bifurcation (n=71)**	**P**	**Pre-Bifurcation (n=71)**	**Post-Bifurcation (n=71)**	**P**
Renal Vein	63	55	0.115	59	53	0.286
IVC	35	12	<0.001	35	11	<0.001
Psoas Muscles	5	17	0.004	4	15	0.003
Small Bowel	5	15	0.041	2	8	0.109
Liver	1	8	0.016	1	3	0.500
Pancreas	3	6	0.250	2	6	0.125
Adrenal	4	2	0.625	3	1	0.625
Diaphragm	4	1	0.250	2	1	1.000
Splenic Artery	1	1	1.000	0	1	1.000
Splenic Vein	1	0	1.000	0	0	