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# **Impact of cone beam - CT on adrenal vein sampling in primary aldosteronism**

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None.

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# **Impact of cone beam - CT on adrenal vein sampling in primary aldosteronism**

## **KEYWORDS**

Primary aldosteronism, Cone-Beam Computed Tomography, Angiography, Adrenal vein sampling, Right adrenal vein cannulation, Radiation Exposure

## **ABBREVIATIONS AND ACRONYMS:**

ABPM: ambulatory blood pressure monitoring

AVS = Adrenal vein sampling

CB-CT = Cone-Beam Computed Tomography

DAP = Dose area product

LAV = Left adrenal vein sampling

LI = Lateralization index

PA = Primary aldosteronism

RAV = Right adrenal vein sampling

SI = Selectivity index

## **ABSTRACT**

### **Purpose:**

The aim of this study in a group of patients with primary aldosteronism was to evaluate the contribution of CB-CT (cone beam CT) to the overall success rate of adrenal vein sampling (AVS), and in particular to the selective cannulation of the right adrenal vein (RAV).

### **Method:**

This was a retrospective single-center study including 91 AVS procedures performed by our consultant radiologist between March 2011 and January 2017. Fifty cases were performed with CB-CT and 50 were performed without. Angiography with CB-CT was carried out after RAV cannulation to check the accurate catheter position. For each patient, we collected technical and biochemical success rates, as well as irradiation data.

### **Results:**

The overall success rate of AVS with CB-CT was 80%, vs. 44% without ( $p=0.00046$ ), with right-sided selectivity of 88% vs. 49% ( $p<0.0001$ ). There was no significant increase in radiation exposure with CB-CT ( $p=0.8206$ ). Fluoroscopy time and quantity of iodine injected were significantly lower with CB-CT than without ( $p=0.0039$  and  $p<0.0001$ ).

### **Conclusion:**

CB-CT allows a better evaluation of the selectivity of right-sided adrenal catheterization and greatly increases the overall success rate of AVS.

## INTRODUCTION

Primary aldosteronism (PA) is the most common cause of secondary hypertension[1]. Its exact prevalence remains variable and controversial. However, the most recent studies estimate prevalence to be 5% of the general hypertensive population, and 10% of patients managed in hypertension referral centers[2][3][4][5]. Diagnosis and treatment are particularly important because PA is associated with a higher risk of cardiovascular and cerebrovascular pathologies than essential hypertension[6][7][8]. The two most common causes of PA are bilateral hyperaldosteronism and aldosterone-producing adenoma. While bilateral hyperaldosteronism leads to lifelong anti-aldosterone medical management, secreting adenomas can be treated surgically with unilateral adrenalectomy.

After hormonal confirmation of PA, an adrenal computed tomography (CT) scan is performed. However, in most cases, adrenal imaging alone fails to detect a microadenoma due to its lack of sensitivity[9][10]. Moreover, a few adenomas revealed by CT scan may be non-secreting, thus revealing a lack of specificity[9]. Consequently, the current recommendation is to perform bilateral adrenal venous sampling (AVS), especially in patients older than 35 years[11], to allow identification of unilateral aldosterone production prior to considering adrenalectomy[9]. Nevertheless, AVS remains an invasive and demanding technique that requires an experienced radiologist, with an estimated risk of lesion of the adrenal vein in the range of 0.6%[11]. For these reasons, AVS is underused and restricted to expert centers[12].

The main technical limitation of AVS consists in selective catheterization of the right adrenal vein (RAV), mainly due to its complex and variable anatomy. To overcome this difficulty, radiologists can use Cone-Beam Computed Tomography (CB-CT) which produces images similar to those of CT scan, thanks to the use of rotational angiography to ensure appropriate positioning of the sampling catheter in the RAV[13]. To our knowledge, no study has yet validated its impact on the overall success rate of the procedure.

Thus, the aim of the study was to assess whether the use of CB-CT impacts the overall success rate of AVS, and especially the rate of selective catheterization of the RAV.

## **MATERIAL AND METHODS**

The privacy rights of human subjects were observed in agreement with the local laws. In a descriptive retrospective single-center study, patients referred to the Department of Arterial Hypertension and Therapeutics, who had hypertension with proven primary aldosteronism (PA) and who underwent AVS with or without CB-CT were included between March 2011 and January 2017. Patients underwent diagnosis of PA according to standard recommendations[11]. Plasma aldosterone and active renin concentrations were measured twice in the supine position and after 15 minutes in the upright position: an aldosterone-to-renin-ratio of 23 ng/ng or greater confirmed the diagnosis of PA. Patients had previously undergone adrenal CT scans. All patients who underwent AVS performed by our specialized radiologist were included consecutively. AVS performed either for other reasons than diagnosis of PA or done by another radiologist were excluded. We compared two groups of patients, one undergoing AVS with CB-CT and the other without. Collection of clinical data (gender, age, physical measurements, 24-hour ambulatory blood pressure monitoring, number of antihypertensive drugs), laboratory results (kalemia, plasma aldosterone, and plasma renin activity supine/upright), and radiological data (adenoma or hyperplasia, localization, size), were extracted from patients' electronic medical records, and from the digital archiving system for radiological images. Adverse events due to AVS were reported. We also compared AVS procedures with and without CB-CT, Dose Area Products (DAP), and times of fluoroscopy of AVS in both groups. Furthermore, the amount of iodine injected in each procedure was collected to compare consumption of contrast agent in the two methods.

### **Assay**

Plasma aldosterone concentrations were measured by radio-immuno assay. Plasma active renin and plasma cortisol were measured by immunochemiluminometry (Liaison, Diasorin and Cobas-6000).

### **AVS procedure**

All patients included gave their written informed consent to participate in the procedure. In both groups, AVS was performed in the radiology department without ACTH stimulation, under local anesthesia, early in the morning and after the patient had

spent the night in a supine position. Any antihypertensive medications likely to interfere with the hormonal dosages had been stopped according to recommendations[14]. Venous access was obtained by puncture of the right common femoral vein, under ultrasound control or not, by placement of a short 5F introducer. The right adrenal vein was first catheterized with a 5F Terumo® femoral-renal catheter measuring 80cm. Then, an 80-cm 5F Terumo® femoral-renal-left catheter was used to catheterize the left adrenal vein. Finally, the inferior vena cava was sampled to validate catheterization selectivity. Aldosterone and cortisol plasma concentrations were measured from samples from the inferior vena cava and both adrenal veins. For the group with CB-CT, AVS was performed in a room equipped with a flat dynamic sensor (DISCOVERY IGS 740, General Electric®, Little Chalfont, United Kingdom). In this case, the position of the catheter within the right adrenal vein was checked by 3D angiography (FOV of 40cm, injection of 6cc to 1cc/s, one second delay of injection before the start of the 200°rotation, with delivered constants automatically optimized by the system, rotation time, speed...). 3D multi-planar reconstructions were then directly posted on the control monitor to assess the position of the catheter (Figure 1)[14][13]. In the group without CB-CT, AVS procedures were also performed in a room equipped with a flat dynamic sensor, (ADVANTX LCA, General Electric®, Little Chalfont, United Kingdom). Confirmation of the appropriate position of the catheters in the adrenal veins was carried out with automated small output injection angiography.

### **Choice of SI and LI and concordance between sectional imaging and selective AVS**

Selectivity indices (ratio of adrenal vein cortisol/inferior vena cava cortisol) (SI) were calculated for both adrenal veins. Success rate of AVS was defined by selective catheterization of both adrenal veins (SI>2). Lateralization of adrenal aldosterone secretion was considered effective when the lateralization index (LI) was greater than 4 (defined as the aldosterone-to-cortisol-ratio between the dominant and non-dominant adrenal vein) [9][11]. Then, AVS results were compared to CT scan results to evaluate the concordance rate in patients with aldosterone-producing adenoma. Typical adenoma was defined as a well-defined nodule with either a spontaneous density <10 HU or an absolute washout threshold of 60% (relative washout at 40%) on CT, or a 20

% signal intensity decrease in the nodule between in-phase and opposed-phase images on MRI [15][16][17].

## **Statistical Analysis**

We provide descriptive values and qualitative variables with sizes and percentages as well as quantitative variables shown as their means  $\pm$  standard deviation. The alpha risk was 5%. A Shapiro-Wilk test was carried out to determine the normal distribution of our variables. We subsequently compared the groups using Student, Mann-Whitney or Fisher tests as appropriate. All statistical analyses were performed using Medcalc 18© (MedCalc Software bvba, Ostend, Belgium).

## RESULTS

### Study population

Between March 2011 and January 2017, 124 AVS were performed by our specialized radiologist and 91 were included: 50 with CB-CT and 41 without (Figure 2). The main characteristics of the patients are shown in Table 1. Mean age was 52 years (range: 29 - 78). Mean 24-h SBP and DBP were  $144\pm 22$  and  $86\pm 15$  mmHg. The characteristics of the two groups are shown in Table 2. They did not differ significantly except for gender, with more men in the group without CB-CT than in the group with it: 80.5 % (33/41) versus 58 % (29/50).

### Success rate of AVS

Fifty-eight patients, i.e. 67.7% of all patients who underwent AVS, had successful bilateral AVS. In the group with CB-CT, the median selectivity index of RAV was 12.36 [0.22; 79.16] vs. 3.22 [0.52; 453.38] without CB-CT ( $p=0.0066$ ). In the group with CB-CT, the median lateralization index was 7.62 [1.22; 510.46] vs. 3.97 [1.07; 196.28] without CB-CT ( $p=0.1564$ ). In the group with CB-CT, the overall success rate was 80% (40/ 50), CI 95% (67-92) versus 44% of AVS without CB-CT (18/41), CI 95% (28-60) ( $p=0.00046$ ). In the group with CB-CT, the selective catheterization rate of RAV was 88% (44/ 50), CI 95% (79-97) vs. 49% of AVS without CB-CT (20/41), CI 95% (33-65) ( $p<0.0001$ ) (Figure 3).

### Adverse events, radioprotection, contrast agent

Only one (1.1%) minor complication occurred. It concerned an inguinal hematoma at the puncture site that resolved spontaneously. No major complication was noted. Fluoroscopy time was shorter, and quantity of iodine injected was significantly lower in the group with CB-CT than in the group without ( $p<0.0001$ ). There was no significant difference regarding total DAP (Table 3).

## **Concordance between selective AVS and imaging**

The results of the 58 successful AVS ( $SI > 2$ ) in terms of lateralization ( $LI > 4$ ) or not were compared to the imaging data to evaluate the rate of concordance. Thirty-eight patients had a lateralization of aldosterone secretion on the same side of the nodule evidenced on imaging and 4 patients on the contralateral side. Sixteen patients, i.e. 27.5% of successful AVS, did not demonstrate any lateralization of aldosterone secretion, even though a nodule was present on CT. The rate of non-concordance between imaging and AVS was therefore 35% (20/58).

## DISCUSSION

In this sample of patients with primary aldosteronism, there was a significant improvement in the success rate of AVS when performed with CB-CT, increasing from 44% without CB-CT to 80% with it. This progression was due to a significant increase in the RAV selective catheterization rate, which rose from 49% without CB-CT to 88% with it ( $p<0.0001$ ).

The overall success rates of AVS without CB-CT range from 30% to 95% [10][12][18][19]. This difference might be due to the definitions of SI and types of AVS procedures that the authors used. In our study, since patients were under unstimulated conditions and to minimize the risk of false negatives, we used a  $SI>2$  as recommended by consensus [20,21]. Regarding the use of CB-CT, recent studies suggest that it might promote successful cannulation and lateralization of the RAV, thereby increasing the success rate [13][22][23][24]. In two Asian studies, the success rates were 95.2% and 95.7% [23][24]. Nonetheless, to our knowledge, no study has yet compared the total success rate of AVS performed with the help of CB-CT with AVS performed without CB-CT, as prior investigations either evaluated only right adrenal venous catheterization using CB-CT, or used costly hormonal methods such as quick cortisol assay protocols[23][25]. Our findings suggest that the use of CB-CT improves the outcome of AVS. While some authors have argued that use of CB-CT increases the radiation doses delivered to the patient, there was no significant increase in DAP with CB-CT in our series ( $p=0.8206$ ). This was probably due to optimized constants delivered with CB-CT, and to improvements in the quality of the dedicated equipment and fluoroscopy. This probably also impacted the time to perform fluoroscopy, which was significantly shorter ( $p=0.0039$ ).

Compared to CT scans, 4 patients demonstrated lateralization on the contralateral side of the nodule and 16 patients had an adenoma without AVS-proven lateralization. Thus, the rate of discordance between CT and AVS was 35%, which is similar to those reported in the literature. A meta-analysis of 38 studies including 950 patients found that neither CT scan nor MRI was able to diagnose the cause of PA in 37.8% of cases when AVS was used as a reference test to establish lateralization of aldosterone secretion[26]. While

the role of AVS continues to be debated, it remains the most reliable technique to distinguish the causes of PA according to recent recommendations and to establish the appropriate surgical treatment[9][27][11][20][21]. However, in the SPARTACUS prospective trial that evaluated the performance of CT alone versus AVS for therapeutic decision-making, AVS and CT scan were comparable in allocating patients for the correct management of PA and did not demonstrate any significant difference in clinical benefit after 1 year of follow-up[28]. However, the SPARTACUS AVS protocol and ours are not comparable since the cut-off values to define selectivity indexes were different. The results in the SPARTACUS trial may not apply to AVS procedures without cosyntropin stimulation, as stated by the authors[28].

Our study has some limitations. First, it was a retrospective single-center study. However, only a few centers use AVS to manage PA. Second, our two groups were not strictly comparable. However, they differed only in gender ratio but not in age or BMI. Our global success rate with CB-CT is low compared to some other studies and could be improved by the addition of hormonal methods such as a quick cortisol assay [25]. Finally, the use of CB-CT on the left adrenal vein was not evaluated and could be the subject of another study. This is especially important since there was an 8% difference between the RAV sampling success rate and the total success rate of AVS (88% vs 80%).

In conclusion, the present findings demonstrate the rationale of combining the gold standard AVS with CB-CT for the therapeutic management of patients with hypertension and PA, in addition to CT scan. CB-CT allows better assessment of the selectivity of right-sided adrenal cannulation and greatly increases the overall success rate of AVS.

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## FIGURE CAPTIONS

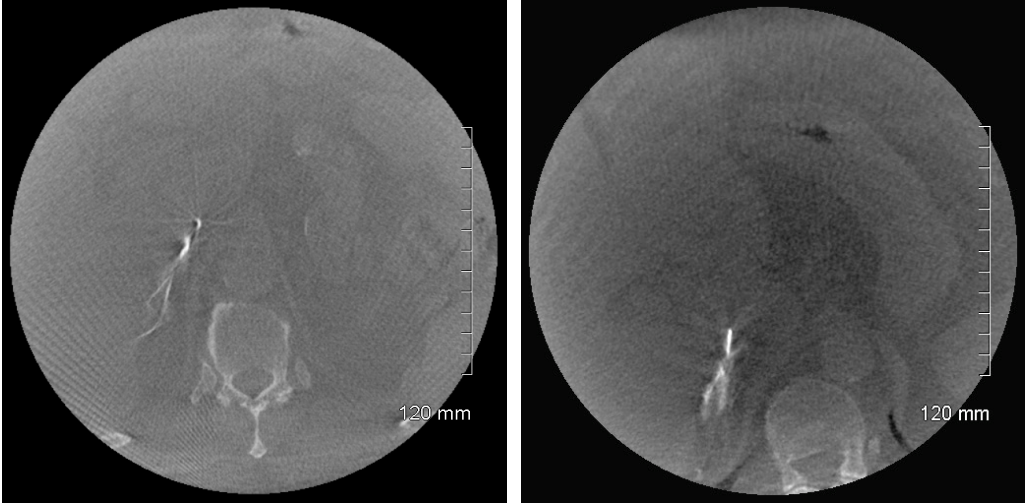
**Figure 1.** CB-CT acquisitions (A, B) 2D reconstructions, confirming correct position of distal end of catheter within RAV (C, D, E, F) 3D reconstructions of right adrenals.

**Figure 2.** Flow chart of study population.

**Figure 3.** Overall success rate and selective right-sided catheterization with and without CB-CT

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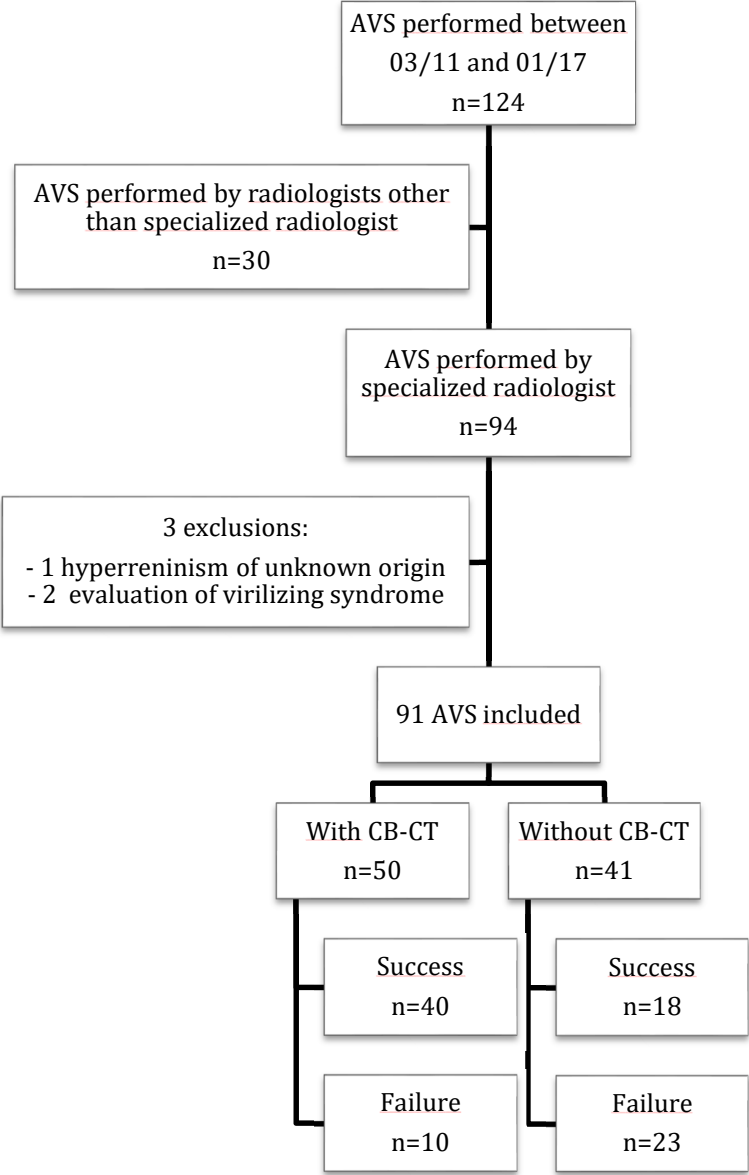
A and B



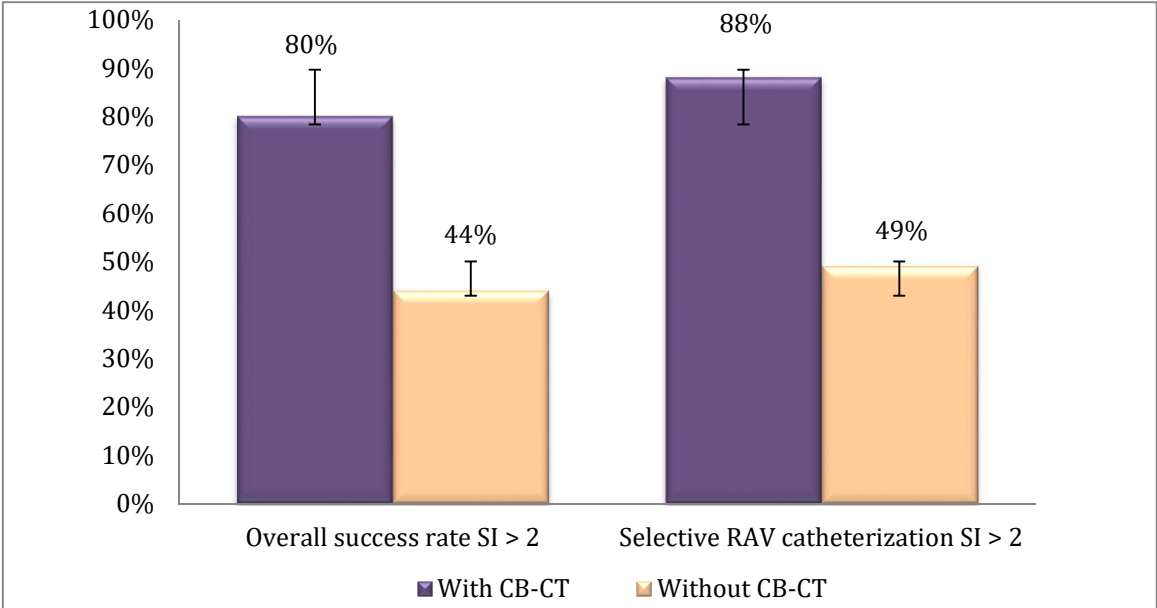
C, D, E, F



**Figure 2:** Flow chart of study population



**Figure 3:** Overall success rate and selective right-sided catheterization with and without CB-CT



**Table 1:** Baseline characteristics (mean  $\pm$  SD)

	<b>Total population n= 91</b>
<b>Men (n (%))</b>	58 (64)
<b>Age (years)</b>	52 $\pm$ 11
<b>Morphologic data</b>	
<b>Weight (kg)</b>	87 $\pm$ 19
<b>Height (m)</b>	1.72 $\pm$ 0.08
<b>BMI (kg/m<sup>2</sup>)</b>	29.0 $\pm$ 5.1
<b>Blood pressure data in ABPM</b>	
<b>Diurnal SBP (mmHg)</b>	145 $\pm$ 22
<b>Diurnal DBP (mmHg)</b>	89 $\pm$ 13
<b>Nocturnal SBP (mmHg)</b>	137 $\pm$ 23
<b>Nocturnal DBP (mmHg)</b>	82 $\pm$ 14
<b>24-hour SBP (mmHg)</b>	144 $\pm$ 22
<b>24-hour DBP (mmHg)</b>	86 $\pm$ 15
<b>Number of antihypertensive medications</b>	3.9 $\pm$ 1.2
<b>Assays</b>	
<b>Lowest kalemia (mmol/l)</b>	3.0 $\pm$ 0.4
<b>Plasma Supine Aldosterone (ng/l)</b>	372 $\pm$ 328
<b>Plasma upright Aldosterone (ng/l)</b>	577 $\pm$ 572
<b>Plasma supine active renin (<math>\mu</math>IU/ml)</b>	5.8 $\pm$ 3.2
<b>Plasma upright active renin (<math>\mu</math>IU/ml)</b>	9.5 $\pm$ 5.6
<b>Aldosterone-to-renin ratio</b>	78 $\pm$ 67

**Normal values:** K<sup>+</sup> (3.5-5 mmol/l), Plasma Supine Aldosterone (49.3-175 ng/l) and standing (34.7-275 ng/l), Plasma supine active renin (4.2 – 59.7  $\mu$ IU/ml) and standing (5.3 – 99.1  $\mu$ UI/ml), Aldosterone-to-renin ratio <23  
 ABPM: ambulatory blood pressure monitoring

**Table 2:** Demographics characteristics of both groups (mean  $\pm$  SD)

	<b>With CB-CT n = 50</b>	<b>Without CB-CT n = 41</b>	<b><i>p</i></b>
<b>Age (years)</b>	50 $\pm$ 10	54 $\pm$ 11	0.0902
<b>Men (n(%))</b>	29 (58.0)	33 (80.5)	<b>0.0254</b>
<b>BMI (kg/m<sup>2</sup>)</b>	30.2 $\pm$ 5.1	29.0 $\pm$ 5.1	0.2817

**Table 3:** Fluoroscopy data and amount of iodine for both groups (mean  $\pm$  SD)

	<b>With CB-CT</b>	<b>Without CB-CT</b>	<b><i>p</i></b>
<b>Time of fluoroscopy (minutes)</b>	9 $\pm$ 6	15 $\pm$ 10	<b>0.0039</b>
<b>Total DAP (cGy .cm<sup>2</sup>)</b>	5549 $\pm$ 5045	5212 $\pm$ 4094	0.8206
<b>Amount of iodine (ml)</b>	45 $\pm$ 29	91 $\pm$ 58	<b>&lt; 0.0001</b>

DAP: Dose area product