Failure Mode Analysis in Adrenal Vein Sampling: A Single-Center Experience

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ABSTRACT

Purpose: To analyze failure modes in a high-volume adrenal vein sampling (AVS) practice in an effort to identify preventable causes of nondiagnostic sampling.

Materials and Methods: A retrospective database was constructed containing 343 AVS procedures performed over a 10-year period. Each nondiagnostic AVS procedure was reviewed for failure mode and correlated with results of any repeat AVS. Data collected included selectivity index, lateralization index, adrenalectomy outcomes if performed, and details of AVS procedure. All AVS procedures were performed after cosyntropin stimulation, using sequential technique.

Results: AVS was nondiagnostic in 12 of 343 (3.5%) primary procedures and 2 secondary procedures. Failure was right-sided in 8 (57%) procedures, left-sided in 4 (29%) procedures, bilateral in 1 procedure, and neither in 1 procedure (laboratory error). Failure modes included diluted sample from correctly identified vein (n = 7 [50%]; 3 right and 4 left), vessel misidentified as adrenal vein (n = 3 [21%]; all right), failure to locate an adrenal vein (n = 2 [14%]; both right), cosyntropin stimulation failure (n = 1 [7%]; diagnostic by nonstimulated criteria), and laboratory error (n = 1 [7%]; specimen loss). A second AVS procedure was diagnostic in three of five cases (60%), and a third AVS procedure was diagnostic in one of one case (100%). Among the eight patients in whom AVS ultimately was not diagnostic, four underwent adrenalectomy based on diluted AVS samples, and one underwent adrenalectomy based on imaging; all five experienced improvement in aldosteronism.

Conclusions: A substantial percentage of AVS failures occur on the left, all related to dilution. Even when technically nondiagnostic per strict criteria, some "failed" AVS procedures may be sufficient to guide therapy. Repeat AVS has a good yield.

ABBREVIATIONS

AVS = adrenal vein sampling, IVC = inferior vena cava, SI = selectivity index

Adrenal vein sampling (AVS) plays a critical role in the management of primary aldosteronism, serving as the final determinant between surgical and medical management. Primary aldosteronism is relatively common, estimated to affect 5%–13% of patients in specialty hypertension clinics (1–3). There has been increased recognition of primary aldosteronism with an associated resurgence of interest in AVS, a procedure that has been in use for decades yet lacks widespread penetration even within the interventional radiology (IR) community (1,4). One of the principal reasons for this disconnect is the perception, supported by considerable literature, that AVS is an unreliable, heavily operator-dependent modality with a failure rate as high as 70% even in experienced hands (1,3,5,6). Nonetheless, evidence-based guidelines continue to promote AVS as having a key role in management of primary aldosteronism (3), and consequently several approaches to improve AVS results have emerged. These approaches include the use of relatively new technologies, such as cone-beam computed tomography (CT) (7) and CT venography (8), more efficient laboratory-IR interaction with the so-called rapid cortisol assay approach (9,10), and technical enhancements involving catheter shapes (11) and anatomic cues such as the inferior accessory hepatic vein

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and the inferior emissary vein (11–13). The literature has focused considerably on AVS failure, and this failure is considered to have prevented its more widespread adoption. The purpose of this study was to use failure mode analysis in an effort to determine which components of the AVS process contributed to nondiagnostic AVS procedures

MATERIALS AND METHODS

This retrospective analysis was approved by the institutional review board and carried out in full compliance with the Health Insurance Portability and Accountability Act; consent waiver was obtained. A database was constructed from our division's main quality assurance database (Hi-IQ; ConexSys, Lincoln, Rhode Island) of all AVS procedures performed over a 10-year period ending in March 2013. Data collected included patient demographics, presence or absence of an adrenal mass on imaging, procedural cortisol and aldosterone levels, and success rate. For all procedures in which AVS failure occurred for any reason, a detailed analysis of the reasons for failure was undertaken, examining every step from patient intake to eventual success or abandonment of AVS. Similar details were obtained for any repeat procedures in these patients. Outcome of adrenalectomy, if performed, was recorded.

All patients referred for AVS were screened using a standard intake procedure. This procedure included obtaining values for aldosterone and renin; calculation of an aldosterone-to-renin ratio; obtaining the results of any imaging; determining any potentially problematic medications (see later); and obtaining other relevant laboratory data, such as potassium, creatinine, and coagulation parameters. After confirming that the available laboratory data supported a diagnosis of primary aldosteronism, patients were scheduled for AVS. Patients taking mineralocorticoid receptor antagonists (eplerenone, spironolactone), aliskiren, or amiloride were asked to withhold these medications for 2 weeks. AVS was performed by a single operator with > 20 years' experience in AVS, using the standardized Mayo Clinic post-stimulation sequential protocol (14) with minor modification (15). In brief, cosyntropin (CORTROSYN; Amphastar Pharmaceuticals, Rancho Cucamonga, California) 0.25 mg/500 mL was infused at 100 mL/h for a minimum of 1 hour before and throughout the procedure. All initial AVS procedures were performed via a right common femoral vein approach using standardized catheters, including RDC (Cook, Inc, Bloomington, Indiana) for the right, Simmons 2 (Cordis Corp, Warren, New Jersey) for the left, and later Simmons 3 (Terumo, Somerset, New Jersey) for the left (see later), to start, followed as needed by additional catheter shapes. All catheters had a single 0.025-inch side hole punched approximately 1 mm from the tip; for right-sided catheters, this was on the cephalad aspect, and for the left-sided Simmons 3 catheter, it was on the inside of the curve (ie, facing laterally when selective in the adrenal-phrenic trunk or left adrenal vein). If considered necessary by the operator, a microcatheter (Renegade Hi-Flo; Boston Scientific, Natick, Massachusetts) was used through the 5-F catheter. A single sample was obtained by gentle aspiration from each adrenal vein and from the infrarenal inferior vena cava (IVC), beginning with the right adrenal. Cone-beam CT, preoperative CT venography (see later), or "rapid cortisol assay" was not routinely used. Procedures were always performed on an outpatient basis under moderate sedation with intravenous (IV) midazolam and fentanyl, titrated to effect. Laboratory specimens were initially hand carried to the laboratory where a receipt was signed by Specimen Receiving; in later years (see later), a dedicated laboratory technician was assigned to pick up the specimens personally from the IR suite and oversee processing of the specimens. Cortisol determinations were performed in-house, and aldosterone determinations were sent to a reference laboratory (ARUP Laboratories, Salt Lake City, Utah) resulting in a 1-week lag between obtaining cortisol and aldosterone results. Generally, if the cortisol results showed the procedure to be nondiagnostic, the aldosterone determination was cancelled to save the patient unnecessary costs; however, if there was dilution, but the selectivity index (SI = adrenal cortisol/IVC cortisol) was > 1 (see later), the aldosterone determination proceeded. Likewise, if there was difficulty in identifying a right adrenal vein, the right-side and IVC cortisol samples were run first, and if nondiagnostic, the left-side specimen was not assayed to save costs. When a successful sampling was determined (< 24 hours), patients who had withheld mineralocorticoid receptor antagonists or other agents were told to resume their medications, pending the final aldosterone results. Patients were notified of the final AVS result interpretation by the performing physician usually on the day the results were received. In the event of a failed procedure, patients were offered another attempt at AVS, and depending on the immediate reason for failure, additional imaging with CT venography was performed (n = 2), or a different approach (right internal jugular, to allow a different perspective for the various catheter shapes) was used (n = 2) in subsequent AVS attempts.

Although there is considerable variation in definitions of a "successful" sampling (3), the standard definitions of SI (adrenal cortisol/IVC cortisol) and lateralization index (higher aldosterone-to-cortisol ratio/lower aldosterone-to-cortisol ratio) were applied uniformly throughout the study period: SI of ≥ 5 was considered diagnostic (ie, "successful"), and lateralization index of ≥ 4 was an indication for adrenalectomy. Contralateral suppression was taken into account when interpreting the results; however, no formal contralateral suppression index was used.