WFUMB Position Paper. Incidental Findings, how to manage:

Adrenal incidentaloma (AI)

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1 ABSTRACT

Focal lesions of the adrenal glands are incidentally detected in approximately 5% of cases by modern imaging techniques. Less than 5% of these adrenal incidentalomas are malignant and approximately 10% have endocrine activity. Reliable differentiation of malignant versus benign and hormonal active versus non-functional adrenal incidentalomas significantly influences therapeutic management and outcome of affected individuals. Therefore, each adrenal incidentaloma should undergo a standardized diagnostic work-up to exclude malignancy and endocrine activity. This position statement of the World Federation of Ultrasound in Medicine and Biology (WFUMB) summarizes the available evidence on management of adrenal incidentaloma and describes efficient management strategies with particular reference to the role of ultrasound techniques.

2 SUMMARY STATEMENTS

- All patients with AI > 10 mm should be evaluated at initial presentation to exclude malignancy and hormonal hyperfunction according to recent guideline recommendations [1].
- In the case of a “benign imaging phenotype” with ultrasound, additional unenhanced CT should be performed in all lesions ≥ 10 mm which are not completely anechoic with smooth borders (typical cyst).
- AI < 40 mm, smooth border and CT attenuation value < 10 HU are most probably benign. After exclusion of hormonal activity further diagnostic work-up is not recommended. However, it is recommended to compare with any prior imaging examination to evaluate any change in size.
- AI ≥ 40 – 60 mm and/ or with hormonal activity should be considered for surgery.
- Adrenocortical carcinoma is typically characterized by irregular shape, inhomogeneous echopattern, calcifications and non-enhancing spontaneous hemorrhage necrosis and higher CT attenuation values > 20 HU and delayed wash-out (contrast enhanced CT).
Pheochromocytoma are typically > 30 - 40 mm at time of diagnosis, highly vascularized with regressive changes with zones of spontaneous necrosis, sometime ectopic and multiple. Final diagnosis is established by measuring plasma metanephrines.

Cushing's syndrome is excluded by performing the 1 mg overnight dexamethasone suppression test.

Typical imaging features of Conn syndrome is the size of < 20 mm, oval or round, sharp delineated and homogeneous echopattern. Diagnosis should be approached in patients with arterial hypertension, and/or otherwise unexplained hypokalemia, using the plasma aldosterone concentration to plasma renin activity ratio.

US should be considered in cases with recommended imaging follow-up, if appropriate US visualization of the mass lesion is possible.

In patients with a known primary malignancy elsewhere the probability of an adrenal mass being metastatic is much higher compared to healthy subjects.

Histological sampling (US/EUS- or CT-guided) may be considered on an individual basis in patients with AI measuring > 40 mm and < 60 mm or with no definite benign imaging phenotype with imaging or in the case of metastasis (incidentally discovered cancer), if patient-related factors strongly rule out surgery. It has high clinical value in all cases with a history or suspicion of malignancy.
The definition of an adrenal incidentaloma (AI) refers to any focal adrenal lesion, independent of size, discovered by any imaging method including ultrasound (US), endoscopic ultrasound (EUS), computed tomography (CT) or magnetic resonance imaging (MRI), in the absence of adrenal disease.

Due to the fact that the adrenal glands are the fourth most frequent site of metastasis, independent of location of the primary tumor (prevalence of metastases 27 %) [2-4]. The definition excludes adrenal lesions which are detected in patients with suspected or established diagnosis of malignancy [1,5,6]. However, in patients with known malignancy, more than 50% (9 % - 75%) of solid adrenal masses turn out not to be metastases [7]. Whereas the published literature is full of CT reports, comparatively little is published for US, which is still the imaging method with the best detail resolution. Conventional US and EUS both allow visualization of the normal adrenal gland and its vascularity [(Fig. 1, 2)]. It is possible to detect focal lesions down to 3 - 5 mm, in particular with transabdominal US for the right gland and with EUS for the left one [7-9] [(Fig. 3, 4)]. Nevertheless some definitions include only adrenal mass lesions ≥ 10 mm [10,11], as the normal thickness of the body of the adrenal gland varies from 6 to 8 mm ± 2 mm [12]. The most frequent pathology underlying an AI is a non-functional adenoma [7,11].

After detection of an adrenal incidentaloma there are a few important questions to be answered to determine the need for treatment.

- What is the prevalence?
- Is the AI malignant?
- Has the AI endocrine activity?

### 4 ADRENAL INCIDENTALOMA

#### 4.1 Prevalence

The prevalence of AI of any size with imaging is reported to be about 5 %, with a range from 1% – 12 % (being higher in the older age group) and approaches the frequency of up to 8.7% found in autopsy series [13,14]. In patients with high body mass index (BMI), presence of diabetes mellitus and arterial hypertension, the prevalence is even higher [15,16]. Bilateral AI
are found in about 10% - 15% of cases [17-19]. In unselected healthy subjects and in patients with inflammatory bowel disease, a prevalence of 5% was reported using abdominal US [8,20-22]. By far the largest data have been collected using CT. With state-of-the-art contemporary CT examinations, AI was found in 4.4% - 5% of individuals [23-25]. In older studies the reported prevalence was much lower for both methods, with 259/61054 (0.4%) AI using CT performed from 1985 to 1990 [26] or 0.1% [27], or less [28] using abdominal sonography. Therefore, AI was described to be “a ‘disease’ of modern imaging technology” [29]. The main role of imaging is therefore to limit invasive management of AI, and particularly the number of surgical adrenalectomy and biopsies.

4.2 Is the AI malignant?

As shown for focal liver lesions [30,31] but also in AI, primary or secondary malignancies in asymptomatic subjects, is not a common finding [11,15,32-34]. The most recent systematic review found a mean prevalence of adrenocortical carcinoma of 1.9% (median 1.4%) and metastases of 0.7% (median 0.2%). It concluded that due to various biases and misinterpretation of reports, previous reviews have overestimated the risk of an AI to be malignant. According to newer data, the real cumulative risk of malignancy in AI may be below 3% [11].

4.2.1 Size

Importantly the size and some imaging features are helpful to determine if an AI is benign or malignant [33-35]. It could be shown that a diameter > 40 mm is a crucial parameter since > 90% of adrenocortical carcinomas are > 40 (-60) mm at the time of diagnosis [17,26,34,36].

On the contrary, the smaller the size at time of diagnosis the better the prognosis [37]. A systematic review showed that only 2% of all adrenal masses ≤ 4 cm turned out to be adrenal carcinoma, whereas the prevalence of adrenocortical carcinoma in adrenal masses of > 4 cm to 6 cm was 6% and in tumors > 6 cm significantly increased to 25% [38]. According to a more recent meta-analysis, the cut-off value of 40 mm for malignancy has an area under the curve (AUC) of 0.92 with high sensitivity (91%), but limited specificity (71%). The pooled positive (3.1) and negative likelihood ratio (LR) (0.13) of this 40 mm cut-off value are not confirmative nor exclusive for malignancy, so that further parameters are needed for definite diagnosis [39].
4.2.2 Imaging features

In addition to the size, some imaging features should be considered. Most important are the smooth border of a lesion and the amount of fat (attenuation values below 10 Hounsfield units (HU) in unenhanced CT) in benign lesions [40-42]. In AI > 40 mm criteria correlating with diagnosis of adenoma vs. adrenocortical carcinoma are; a round shape, the presence of fat, and a precontrast attenuation values less than 10 HU. Moreover an overall impression of a benign lesion (“benign imaging phenotype”) was described to be significantly correlated with the diagnosis of adenoma [43]. In a blinded retrospective study, interobserver agreement was reported to be excellent for precontrast attenuation, substantial for shape, moderate for the presence of fat and fair for overall impression of benignity. Among features of malignancy, the presence of calcifications had a substantial interobserver agreement, whereas agreement for heterogeneity was only fair and for the presence of necrosis marginal [43].

MRI is less often used but the so-called chemical-shift imaging techniques give equivalent results on the estimated amount of fat. The descriptive features for benign AI are: oval or round, sharp margins and smooth contour and homogeneous echopattern (US) or density (CT). In conclusion the combined approach of size (< 40 mm) and HU (≤ 10) excludes malignancy in almost all cases [39,44]. However, approximately 30% of benign adrenal adenomas are lipid-poor with attenuation values of ≥ 10 HU [45].

4.2.3 Contrast-enhanced techniques

Results of studies using contrast enhancement for all imaging methods including contrast-enhanced US are less convincing [7,41,46-51]. Specific quadriphasic contrast-enhanced adrenal CT protocols with higher radiation exposure allow calculation of absolute and relative wash-out [10]. Earlier wash-out in fat containing adenoma and delayed wash-out in metastasis is observed [39,46,47,52-54]. A combination of unenhanced CT and wash-out CT calculation with delayed phase acquisition at 15 minutes for adrenal lesions with attenuation values ≥ 10 HU was shown to provide high sensitivity and specificity for differentiating adenomas from non-adenomas (98% and 92%, respectively) [52]. Delayed contrast-enhanced CT (CE-CT) is more effective for diagnosis than chemical-shift MRI.
With contrast enhanced US, the combination of early arterial hyperenhancement and rapid washout was described to be highly sensitive for the diagnosis of malignancy, but specificity was only moderate [49,50]. Another study did not find significant differences between malignant and benign adrenal masses with regard to the pattern of contrast enhancement [48]. However, contrast enhanced US may be very helpful to detect hypervascularity and intratumoral hemorrhage or necrosis, such as in pheochromocytoma [Fig. 5].

### 4.2.4 Combined imaging criteria

With all imaging techniques, the typical imaging features of adrenocortical carcinoma and metastases are the size > 40 – 60 mm, irregular shape, inhomogeneous echopattern, calcifications and non-enhancing spontaneous hemorrhage necrosis. Metastases tend to be bilateral [39,55–57].

Combining various parameters from unenhanced and contrast enhanced CT and patient-related clinical data significantly improves the diagnostic performance for differentiating between benign and malignant adrenal lesions beyond that of single parameters [58-60]. Other differential diagnosis, e.g., adrenal cysts and myelolipoma, show typical imaging features and do not need further work-up [7,9,61].

### 4.2.5 Image-guided biopsy

In contrast to patients with suspected or proven malignant disease with solid adrenal tumors, in AI the role of image-guided biopsy is limited. Recent guidelines do not recommend image-guided sampling for routine work-up of AIs [1,6,62]. A meta-analysis found a sensitivity and specificity of 87 % and 100 % of percutaneous image-guided biopsy for the diagnosis of malignancy. Definite differentiation of adrenocortical carcinoma from adenoma is not possible in all cases. The pooled complication rate was 2.5 % [63]. For EUS-guided sampling, data are more limited. Diagnostic yield ranges from 76 % to 100 %, and the risk of complications is very low [64-66]. In case of equivocal results of imaging, image-guided sampling aiming at histological specimens may be preferred over adrenalectomy [67]. Pheochromocytoma should be ruled out prior to biopsy [68-70].

### 4.3 Has the AI endocrine activity?
Most AI are nonfunctional (about 90%) [11,34]. A meta-analysis summarized the following data for mean prevalence of functional AI: nonfunctional (89.7%), Cushing’s syndrome 6.4%, pheochromocytoma 3.1% and primary aldosteronism 0.6% [11]. In the large prospective Swedish AI cohort (n=226) the prevalence of endocrine activity was only 3.1% [71]. Pheochromocytoma and (subclinical) Cushing’s syndrome should be excluded in all patients with AI. In patients with arterial hypertension with or without hypokalemia Conn syndrome should be excluded.

4.3.1 Pheochromocytoma

Pheochromocytomas (3% of AI) are typically > (30–40 mm at time of significant hormone production diagnosis [72,73], highly vascularized, sometime ectopic (about 10%) and multiple (about 10%) [11,74,75]. The final diagnosis is achieved by measuring plasma metanephrines. All patients with proven pheochromocytoma should undergo surgery. Multiple endocrine neoplasia should be considered [76,77].

4.3.2 Cushing’s syndrome

Subclinical Cushing’s syndrome (SCS) is defined by autonomous cortisol secretion (detected by ≥ 2 abnormalities of basal or dynamic test of the hypothalamic–pituitary–adrenal axis in patients who do not have the typical signs and symptoms of hypercortisolism. SCS is excluded by performing the 1 mg overnight dexamethasone suppression test (DST) [1]. Cortisol might be secreted either dependent or independently of corticotropin (ACTH). Unilateral adenoma with or without somatic mutations in the cAMP-dependent protein kinase A or bilateral macronodular adrenal hyperplasia (BMAH) are found [78,79]. Recurrent vertebral fractures [80] and less specific arterial hypertension, impaired glucose tolerance or type 2 diabetes mellitus are typical [81-83]. An abnormal DST indicates corticotropin (ACTH)-independent cortisol production [positive if cortisol concentration > 5 µg/dL (> 138 nmol/L)]. As a consequence 24 hour urinary free cortisol, serum ACTH concentration and evaluation of the dehydroepiandrosterone sulfate (DHEAS) metabolism should be performed as well as a high-dose (8 mg) overnight DST. Clinically significant glucocorticoid secretory autonomy is confirmed by an early morning DST serum cortisol. Autonomous glucocorticoid function may also develop over time, therefore follow-up
testing should be considered [33,36,84,85]. However, the efficiency and cost effectiveness of annual repeated testing is not known [11,15]. The indications for unilateral (or very rarely bilateral) adrenalectomy [86] are beyond the scope of this chapter [87-89]. Briefly adrenalectomy is recommended for younger patients with proven subclinical Cushing's syndrome (excess of glucocorticoid secretion) and at risk (e.g., known osteoporosis, arterial hypertension, diabetes mellitus and obesity). The benefits of adrenalectomy in patients with adrenal tumors and SCS has been suggested by a recent meta-analysis [90].

**4.3.3 Hyperaldosteronism and Conn syndrome**

Aldosteronomas (< 1 % of AI) are typically < 20 mm at time of diagnosis, poorly vascularized and most often circumscribed. Diffuse mild hyperplasia < 10 mm can be encountered. The diagnosis is achieved measuring plasma aldosterone concentration to plasma renin activity ratio [33,91].

In younger patients with unilateral aldosterone producing adenoma, surgery should be offered to cure the aldosterone excess whereas in bilateral hyperplasia with hyperaldosteronism and generally in older patients with comorbidity aldosterone-antagonistic drugs are the treatment of choice [92].

**4.3.4 Nonfunctional AI**

Nonfunctional AI (NFAI) should be considered for surgery if > 40 (– 60) mm due to the risk of malignancy, in particular adrenal cortical carcinoma (ACC) [37,91]. The detection of NFAI is predictive for the presence of diabetes mellitus and metabolic syndrome [93,94]. Smaller NFAI may be scheduled for repeated imaging after 6 to 12 months to exclude significant growth and, therefore, malignancy [15]. Significant growth can be assumed by enlargement > 10 mm in diameter during the follow-up period. It should be pointed out that most NFIA that grow are not malignant. The decision for other imaging techniques, the type of imaging for follow up and the time interval is mainly guided by the local circumstances and individual decision. The CT related radiation exposure should be considered [11].

The adrenal myelolipoma (AML) is a slowly growing benign tumor composed of hematopoietic elements and fat elements with eye-catching imaging features [95]. AML is
typically hyperechoic using conventional US and EUS (Fig. 6) and shows abundant fat using CT and MRI.

Many other rare focal adrenal lesions may be encountered.

4.3.5 Bilateral AI

Patients with bilateral AI should be investigated for Morbus Cushing, congenital adrenal hyperplasia and bilateral macronodular adrenal hyperplasia (BMAH) [19,96]. The indication for surgery in bilateral NFAI is more restricted.

4.4 Follow-up

Follow-up by repeat imaging and hormonal work-up is recommended by most recent guidelines for individuals with AI with a benign imaging phenotype and lacking hormonal activity at initial presentation [5,6,10,38,62,97,98]. Adherence to these recommendations seems to be generally poor in clinical practice [99-101]. Moreover, most follow-up studies show a negligible risk of an AI, consistent with a benign and non-functional lesion at initial presentation, to become malignant (0 %) or hormonally active (below 0.3 %) [1,11,71,102].

Based on a systematic review of available data, a review highlighted the high risk of false-positive results of the recommended examinations and cautions that the dose of radiation with CT follow-up confers a risk of fatal cancer that is similar to the risk of the AI to become malignant [11]. Another meta-analysis showed no risk of developing malignancy in 1298 AIs (pooled from 11 studies) followed for a mean of 44.2 month. Size progression was only marginal (pooled mean increment of 0.03 cm), and development of endocrine activity was rare (SCS: 1.8%, Cushing’s syndrome: 0.7%, pheochromocytoma 0.4%) [103]. Therefore, the guidelines of the European Society of Endocrinology (ESE) in 2016 suggested to omit further follow-up imaging in individuals with an adrenal mass < 40 mm and with clear benign features on imaging studies [1]. Moreover, the ESE guidelines suggested against repeated hormonal assessment in individuals with AI, and normal hormonal work-up at the time of initial presentation, unless clinical signs of endocrine activity develop or metabolic co-morbidities or arterial hypertension worsen [1]. Imaging follow-up was recommended for patients with indeterminate adrenal masses opting against adrenalectomy. In case of growth of ≥ 5 mm and enlargement by > 20 % surgical resection is recommended [1]. Other societies suggest using CT protocols with reduced radiation exposure [10] or to individualize follow-up recommendations.
The Polish Society of Endocrinology recommended to use abdominal US for follow-up in appropriate cases [62].

4.5 Adrenalectomy

Adrenalectomy for NFAI < 60 mm is performed most often laparoscopically (less pain, shorter hospitalization, less blood loss, and faster recovery compared to open surgery) but the endoscopic posterior approach [104] and the conventional open surgery (3) are alternatives. Open surgery is recommended in ACC, but the laparoscopic approach can be considered in tumours < 10 cm [105-111].

All procedures are reported to be relatively safe [112].

5 CLINICAL SCENARIOS AND ROLE OF ULTRASOUND

5.1 Detection of AI by transabdominal ultrasound

US has a high sensitivity for the detection of adrenal mass lesions (in particular for the right gland), even in the case of tumors < 20 mm [9]. Therefore, incidental detection of adrenal tumors is a frequent clinical scenario. In a patient/individual without history, suspicion or proof of malignant disease, an AI with a maximum diameter of ≤ 40 mm, homogeneous echo rich echopattern (myelolipoma) and smooth borders or a typical cystic (completely anechoic) pattern ("benign US phenotype") in all likelihood is benign [7]. However, prospective studies comparing the diagnostic accuracy of US to unenhanced CT are lacking. Contrast enhanced US is not helpful to distinguish malignant and benign lesions.

Therefore, in addition to hormonal work-up, unenhanced CT should be performed in lesions ≥ 10 mm. If endocrine activity is lacking and a CT result highly predictive for a benign lesion, further imaging or regular follow-up are not necessary. In the case of equivocal CT findings or hormonal activity, further management should be based on a multidisciplinary expert board discussion. Further management options in cases of functional AI have been described above.

In the case of incidental adrenal mass with equivocal CT criteria or a diameter of >40 mm and < 60 mm an individual decision should be made, considering close follow-up, surgery or further imaging (chemical phase shift MRI) [1]. (E)US- or CT-guided sampling may also be an option in individual cases (e.g. size > 40 mm and < 60 mm or no definite benign imaging phenotype with
imaging plus patient-related factors making surgery less favourable) [4,7]. In smaller lesions hormonal work-up should be performed, and follow-up by ultrasound seems reasonable.

5.2 Detection of AI by cross-sectional imaging (CT, MRI)

In AIs detected using cross-sectional imaging techniques, the role of US and EUS is limited. Performing US may be useful if, as a result of further work-up, surgery is not the appropriate management for the patient and follow-up is required. If US enables appropriate visualization and measurement of the lesion, due to lacking radiation exposure US may be preferred to CT for surveillance [62].

6 REFERENCES

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**Figure 1** Transabdominal ultrasound image of the right adrenal gland (between markers, 34.4 mm length). Anatomical landmarks are the right liver lobe (RLV: right liver vein), the right diaphragm (D) and inferior caval vein (Vena cava inferior, VCI). Layering of the adrenal gland with a hyperechoic central echo representing the medulla, the hypoechoic cortex and hyperechoic capsule are depicted. Thickness of the adrenal gland is below 7 mm (in this case: 5mm).

**Figure 2** Endoscopic ultrasound image of the left adrenal gland, showing the body and two wings as well as the normal layering of the gland as described in Fig. 1. Anatomical landmarks are the pancreatic body and tail (P), upper pole of the left kidney (K) and the left diaphragm (D).

**Figure 3** Two incidental round solid lesions of the right adrenal gland (15 x 13 mm, between markers and 12 x 10 mm) as shown by transabdominal ultrasound. There was no history or suspicion of malignant disease, unenhanced CT showed an attenuation value of below 10 HU, and endocrine work-up did not reveal any endocrine activity (nonfunctional adenoma).

**Figure 4** Very small lesion (6 mm, between markers) of the body of the left adrenal gland, which was found incidentally with endoscopic ultrasound performed for suspected common bile duct stones. The lesion was not found with CT, and hormonal work-up did not show any endocrine activity.

**Figure 5** A large hypoechoic solid lesion of the right adrenal gland (25 x 45 mm) was found incidentally in a patient with arterial hypertension. The lesion had smooth borders, but a central area which was more hypoechoic compared to the periphery of the tumor. Contrast-enhanced ultrasound reveals the high vascularity of the peripheral parts of the tumor, whereas the central area is without any contrast-enhancement (hemorrhage, necrosis, marked by arrows). This pattern indicates the diagnosis of pheochromocytoma which was established by hormonal work-up and finally by surgical pathology.
Figure 6  Transabdominal ultrasound of a huge hyperechoic mass of the right adrenal: the finding is typical for the rare diagnosis of adrenal angiomyolipoma.
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