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Outcome Data From Fabulas: A Feasibility Study Of Radiofrequency Endoscopic Ablation, With Ultrasound Guidance, As A Non-surgical, Adrenal Sparing Treatment For Aldosterone Producing Adenomas

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Introduction: Primary aldosteronism (PA) is potentially curable if due to a unilateral aldosterone producing adenoma (APA), but complete clinical success after adrenalectomy is the exception. Selective radiofrequency ablation (RFA) of the APA, if safe, would lower the bar for intervention, but there are concerns about catecholamine crises, peri-adrenal catastrophes, and ablation of non-functional adenomas. Endoscopic ultrasound (EUS)-guided RFA of left-side APAs is an attractive alternative in which proximity to the stomach enables multiple, short, precise burns as the catheter is steered around the APA. **Aims and Methods:** We conducted a 3-centre feasibility study to determine the safety of EUS-RFA as an adrenal sparing treatment, and assess likely efficacy. The APA was visualised as increased uptake of ¹¹C-metomidate (MTO) in a post-dexamethasone PET CT (1). Initial recruitment was limited to patients in whom surgery was contra-indicated (co-morbidities, ambiguous estimation of unilateral PA). α - and β blockade were introduced 2 weeks prior to RFA, performed under general anaesthesia or deep sedation. Metanephrines were measured before and during RFA. Following diagnostic fine-needle aspiration (FNA), a 5-10 mm19G StarMed™ ablation probe was introduced into the APA. The primary outcome was safety, pre-specified as absence of perforation, haemorrhage, or infarction of major organs on a CT scan performed within 24-48 hours of RFA. Secondary outcomes, at 6 months post-RFA, were PASO criteria for biochemical/clinical success, changes in aldosterone/renin ratio (ARR), BP and drug doses, and in the MTO uptake on repeat scan. **Results:** 28 patients (21 male), age 57.9 ± 10.23 , were studied. 7 patients had 2 ablations. None of the pre-specified serious adverse events occurred. Metanephrines rose in only one patient, given ephedrine and metaraminol. 2 further patients had RFA-related events which delayed discharge but rapidly resolved. 14 patients achieved complete biochemical success and 3 partial. 4 patients achieved complete clinical success and 4 partial. ARR fell from median 3975 (IQR 2090-7475) to 880 (369-2670), $p < 0.001$. BP was unchanged, but on less treatment: number of antihypertensives and defined daily dose fell from 2.9 (95% CI 2.4-3.3) to 2 (1.5-2) and from 4.9 (3.6-6.2) to 2.7 (1.7-3.6) respectively. In 6 patients, MTO uptake into the APA was reduced to $< 50\%$ of adjacent adrenal (indicating complete ablation) whilst the latter was unchanged or minimally reduced in all patients (i.e. preserved function). APA diameter was reduced in 21/28 patients. In 13/28 FNA samples analysed to date, all were positive for CYP11B2 (8/13 strongly and 5/13 weakly positive). **Conclusion:** EUS-guided transgastric RFA is a safe alternative to adrenalectomy for the treatment of left-sided APAs. RFA is now being compared with surgery in a RCT of 110 patients with PA. 1. Wu et al. Nat Med 29:190-202, 2023.

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