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Patient experience of very high power short duration radiofrequency ablation for atrial fibrillation under mild conscious sedation

Gavin Chu[1,2] · Peter Calvert[3] · Bharat Sidhu[2] · Akash Mavilakandy[2] · Ahmed Kotb[2] · Lilith Tovmassian[3] · Nikola Kozhuharov[3,4] · Cédric Biermé[3] · Nathan Denham[3] · Charlene Pius[3] · Jim O'Brien[3] · Wern Yew Ding[3] · Vishal Luther[3] · Richard L. Snowdon[3] · G. André Ng[2,5] · Dhiraj Gupta[3]

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Abstract

Background Very high power short duration (vHPSD) radiofrequency ablation (RFA) may reduce ablation times and improve patient tolerability, permitting pulmonary vein isolation (PVI) under mild conscious sedation (mCS) and promoting same day discharge (SDD).

Methods First, a retrospective feasibility study was performed at 2 tertiary cardiac centres in the UK. Consecutive cases of first-time PVI using vHPSD ablation with 90 W lesions for up to 4 s were compared against cases performed using standard RF (sRF) and cryoballoon (Cryo) therapy. Subsequently, a prospective study of patients who had vHPSD or Cryo exclusively under mCS was undertaken. Questionnaires based on Likert and visual analogue scales (VAS) were used to measure anxiety, discomfort and pain.

Results In total, 182 patients (59 vHPSD, 62 sRF and 61 Cryo) were included in the retrospective study, with 53 (90%) of vHPSD cases successfully performed under mCS. PVI ablation time in the vHPSD group (5.8 ± 1.7 min) was shorter than for sRF (16.5 ± 6.3 min, $p < 0.001$) and Cryo (17.5 ± 5.9 min, $p < 0.001$). Fifty-one vHPSD and 52 Cryo patients were included in the prospective study. PVI ablation time in the vHPSD group was shorter than for the Cryo group (6.4 ± 2.9 min vs 17.9 ± 5.7 min, $p < 0.001$), but overall procedure duration was longer (121 ± 39 min vs 95 ± 20 min, $p < 0.001$). There were no differences in the patient experience of anxiety, discomfort or pain. SDD rates were the same in both groups (61% vs 67%, $p = 0.49$).

Conclusions vHPSD RFA for PVI can be performed under mCS to achieve SDD rates comparable to cryoablation, without compromising patient experience.

Keywords Atrial fibrillation · Conscious sedation · Very high power short duration ablation · Patient experience

1 Background

Radiofrequency (RF) ablation for atrial fibrillation (AF) is preferentially performed under general anaesthesia (GA) to improve procedure tolerance and efficacy [1]. However, GA requires anaesthetic support, has longer recovery times and thus may not naturally lend itself to early mobilisation or to same day discharge (SDD) [2]. AF ablation has therefore found itself at the centre of a "perfect storm" during the SARS-Cov-2 pandemic, where reductions in GA availability [3] have converged with severe pressures on inpatient hospital beds, driving the need for SDD.

In light of this, a very high-power short duration (vHPSD) energy delivery protocol offers multiple potential benefits. Firstly, by reducing RF delivery times, overall procedure

What's new? Pulmonary vein isolation using very high power short duration (vHPSD) radiofrequency ablation (delivering 90 W for up to 4 s per lesion) can be safely and efficaciously performed under mild conscious sedation (mCS);.

Compared to cryoballoon ablation, vHPSD ablation reduces fluoroscopy time and PVI ablation time, but with increased procedure duration;.

The patient experience of vHPSD ablation for atrial fibrillation is similar to that of cryoballoon ablation, and affords similarly high rates of same-day discharge.

✉ Dhiraj Gupta
Dhiraj.Gupta@lhch.nhs.uk

Extended author information available on the last page of the article

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duration is reduced [4]. Secondly, resistive heating, the primary mode of lesion formation using vHPSD [5], results in shallower lesions and therefore may be better tolerated given the epicardial location of cardiac nociceptive nerve endings [6]. These benefits may potentially obviate the need for GA and promote SDD.

We sought to evaluate the early real-world use of first-time AF ablation with a vHPSD approach using mild conscious sedation (mCS) during the SARS-Cov-2 pandemic. In particular, we hypothesised that: (1) the use of vHPSD would deliver safe and successful procedures using mCS whilst also allowing SDD, akin to our well-established cryoballoon (Cryo) ablation programme [7]; (2) the patient experience of vHPSD during mCS would be acceptable when compared with Cryo.

2 Methods

The study was conducted at 2 tertiary cardiac centres in the UK, and comprised of 2 phases. The first phase involved a retrospective, observational feasibility assessment of all patients undergoing first-time AF ablation from September 2020 to August 2021. Procedural metrics of patients who underwent vHPSD ablation, with 90-W lesions for up to 4 s, were compared to patients who had standard RF (sRF) or Cryo ablation. Subsequently, we performed a prospective comparison of AF ablation procedures using vHPSD and Cryo ablation under mCS, with a focus on both patient experience and procedural metrics. Ethics approval was obtained from the institutional review boards, all patients provided written informed consent and the principles of the Declaration of Helsinki were followed.

2.1 Protocol for mild conscious sedation

Non-GA procedures were performed under mCS with intravenous opiates with or without benzodiazepines, delivered by EP nurses under physician direction, without an anaesthetist in attendance. All nurses were trained in management of sedation, and received annual basic life support and advanced cardiac life support training. Equipment needed for resuscitation was available in the catheter laboratory. The on-call anaesthetist was available in case of need for emergency intubation or to facilitate electrical cardioversion. During the procedure, oxygen therapy was administered at 2–4 L/min via nasal cannula, and vital signs including blood pressure, oxygen saturation, heart rate and ECG were monitored continuously.

Conscious sedation was initiated with 0.025–0.05 mg of fentanyl or 5–10 mg of morphine. In addition, intravenous midazolam bolus of 1–2 mg and intravenous infusion of 1 g paracetamol were administered as per operator discretion. An additional dose of 0.025–0.05 mg fentanyl was administered prior to the beginning of RF application. Further fentanyl doses were utilised to control pain and discomfort as and when needed. In case of mild transient oxygen saturation drop < 95%, reclination of the head, enhancement of oxygen therapy and change from nasal cannula to oxygen mask were performed. In case of severe persistent hypoxaemia (oxygen saturation < 90%), intravenous naloxone to reverse fentanyl and/or intravenous flumazenil to reverse midazolam were used, and the on-call anaesthetist was available to facilitate non-invasive ventilation (NIV) or endotracheal intubation (eIT) as necessary.

2.2 Ablation procedural details

Femoral venous access was performed with ultrasound guidance. Arterial sheaths and urinary catheters were not inserted. All patients underwent fluoroscopically guided single or double trans-septal puncture followed by pulmonary vein isolation (PVI), with intravenous heparin targeting an activated clotting time of at least 300 s. Ablation beyond the pulmonary veins (PVs) was performed at the operator's discretion.

In the vHPSD group, following creation of an electroanatomic 3D map, use of the Q Mode Plus (QM+) protocol was mandated for the delivery of left and right wide antral circumferential ablation (WACA). The QM+ protocol uses the QDot Micro catheter in combination with the nGen/nMarQ RF Generator (Biosense Webster, Irvine, CA) to deliver contact force (CF)-guided temperature-controlled RF lesions at 90 W for up to 4 s at a time [8]. RF delivery was delivered in the following order: anterior part of the right WACA, posterior aspect of the right WACA, anterior ridge of the left WACA and then finally the posterior aspect of the left WACA. This was because the most painful part of the PVI procedure is usually the posterior aspect of the left lower PV, partly because this is the thinnest part of the LA, and partly because it is most likely to overlie the oesophagus. Our protocol ensured that patients were likely to be at their deepest level of sedation by the time the potentially most painful ablation was delivered. Point-by-point RF was delivered targeting an interlesion distance of 6 mm on the posterior wall and 5 mm on the anterior wall. Oesophageal temperature monitoring was not performed.

The sRF group had left and right WACA performed using 3D mapping with CF-guided ablation at power settings of up to 50 W [9]. GA RF procedures utilised trans-oesophageal temperature monitoring. Finally, in the Cryo group, the Arctic Front Advance Pro (Medtronic, Minneapolis, MN) or the Polar X (Boston Scientific, Marlborough, MA) catheters were used to deliver 3- to 4-min cryothermy applications to each pulmonary vein (PV).

Protamine was routinely administered at the end of the procedure. Intravenous sheath removal was typically performed with manual pressure to achieve haemostasis or with Z-suture removed after 4 h. No specialised percutaneous closure devices were used. All patients were prescribed 4-h bed rest prior to mobilisation. Post-procedure echocardiography was not mandated.

In the absence of clinical concerns or adverse events at 5 h post-procedure, a default strategy of SDD was applied to all cases that were performed in the morning, based on our previous published guidelines [10], but the final decision for SDD was made by the operator.

2.3 Definition of ablation parameters

We recorded and analysed a number of procedure-related statistics, which are defined below:

- Ablation time — total time taken for ablation delivery (RF time, freeze time, etc.)
- Fluoroscopy time — total time during which x-ray guidance was utilised
- Procedure time — total time taken from needle-to-skin until sheath removal
- LA dwell time — total time during which catheters were present in the LA.

2.4 Study of patient experience

All patients in the prospective study were asked to complete standardised questionnaires assessing their experience of anxiety, discomfort and pain associated with their procedure. The questionnaire was completed between 4 and 24 h after their procedure, and before discharge from hospital. A similar questionnaire was completed by the operator and by the nursing staff immediately after each procedure, recording their assessment of the patient's intraprocedural status. Questions were posed in the form of both Likert and visual analogue scales (VAS), the latter ranging from 0, the "Best state that you can imagine", to 100, the "Worst state that you can imagine". The questionnaires used are presented in the Supplementary Materials.

2.5 Statistical analysis

Continuous variables were expressed as mean ± SD, and compared using *t*-test. Categorical variables were expressed as count (%), and compared using chi-squared or Fisher's exact test. Wilcoxon's rank sum test was used for the comparison of Likert data assuming a linear scale. Paired methods were used when comparing data between patient, nurse and operator. Bonferroni's correction was used when accounting for multiple comparisons. Statistical significance was defined at the two-tailed 5% level. All analyses were performed using R version 4.0.3 (R Foundation for Statistical Computing, Vienna).

3 Results

3.1 Early feasibility assessment

A total of 182 patients (59 vHPSD, 62 sRF, 61 Cryo) undergoing first time PVI were studied, with a mean age of 59 ± 11 years. Seventy-five (41%) were female and 66 (36%) had persistent AF. Baseline data and procedural metrics summarising each of the three groups are shown in Table 1.

Table 1 Baseline demographics and procedural data for feasibility study

	vHPSD ($N=59$)	sRF ($N=62$)		Cryo ($N=61$)	
			p value (vs vHPSD)		*p* value (vs vHPSD)
Age (years)	60.8 ± 9.9	59.2 ± 11.8	0.67	58.2 ± 10.9	0.36
Female, *n* (%)	18 (31)	16 (26)	0.67	19 (31)	0.67
Paroxysmal AF, *n* (%)	41 (70)	33 (53)	0.20	43 (70)	0.67
Moderate or severe LA dilatation, *n* (%)	14 (24)	21 (34)	0.67	9 (15)	0.67
PVI achieved in all PVs, *n* (%)	57 (97%)	62 (100%)	0.47	57 (93%)	0.67
Ablation time for PVI (min)	5.8 ± 1.7	16.5 ± 6.3	< 0.001	17.5 ± 5.9	< 0.001
Patients with ablation beyond PVI, *n* (%)	8 (14%)	20 (32%)	0.036	1 (1.6%)	0.031
Fluoroscopy time (min)	11.5 ± 11.0	6.1 ± 4.6	0.002	18.8 ± 5.7	< 0.001
Procedure duration (min)	118 ± 31	128 ± 40	< 0.001	92 ± 25	< 0.001
Complications, *n* (%)	2 (3.4%)	3 (4.8%)	0.67	1 (1.6%)	0.67
Conscious sedation, *n* (%)	53 (90%)	7 (11%)	< 0.001	59 (97%)	0.32

AF, atrial fibrillation; *LA*, left atrium; *PV*, pulmonary vein; *PVI*, pulmonary vein isolation; *sRF*, standard radiofrequency; *vHPSD*, very high power short duration

The duration of RF energy delivery to achieve PVI using vHPSD (5.8 ± 1.7 min) was significantly shorter than the equivalent duration of both sRF (16.5 ± 6.3 min, $p < 0.001$) and Cryo (17.5 ± 5.9 min, $p < 0.001$). Overall fluoroscopy times were shortest in the sRF group and longest in the Cryo group, whilst for procedure duration, this order was reversed. Successful PVI for all veins was achieved in 57 (96.6%) patients in the vHPSD group, 62 (100%) in the sRF group ($p = 0.47$ compared to vHPSD) and 57 (93.4%) in the Cryo group ($p = 0.67$ compared to vHPSD).

Adjunctive ablation beyond PVI was performed in 8 (14%) patients in the vHPSD group, including posterior wall isolation in 3 patients, CTI ablation in 4 and mitral isthmus ablation in 1. By comparison, 20 (32%) patients underwent additional ablation in the sRF cohort ($p = 0.036$), whilst 1 (1.6%) patient in the cryoablation group received CTI ablation with a RF ablation catheter during the same procedure ($p = 0.031$).

In the vHPSD group, 1 (1.7%) patient had transient global amnesia and was managed as a transient ischemic cerebrovascular event, and 1 (1.7%) had cardiac tamponade that required pericardiocentesis. In the sRF group, 1 (1.6%) patient had cardiac tamponade that resolved following pericardiocentesis, 1 (1.6%) had transient dysphagia that recovered with conservative management and 1 (1.6%) had a chest infection that resolved with antibiotic therapy. In the Cryo group, 1 (1.6%) patient had cardiac tamponade that resolved with pericardiocentesis. There was no significant difference in the number of complications between the groups ($p = 0.67$).

Fifty-three (90%) vHPSD procedures in the early feasibility phase were performed under mCS. Five of the 6 cases where GA was used were performed within the first 3 months of the study period. In this phase, SDD rates were similar in the vHPSD and sRF groups (36% vs 34%, $p = 0.67$) and significantly lower than in the Cryo group (61%, $p = 0.021$).

3.2 Prospective study

One hundred three consecutive patients undergoing first-time AF ablation with either vHPSD ($N = 51$) or Cryo ($N = 52$) ablation were included in the prospective study of mCS. Thirty (29%) patients were female and 74 (72%) had paroxysmal AF.

Table 2 summarises the baseline demographics and procedural metrics for this cohort. vHPSD was associated with lower duration of ablation (6.4 ± 2.9 vs 17.9 ± 5.7 min, $p < 0.001$) and lower fluoroscopy time (7.8 ± 6.7 vs 19.8 ± 7.3 min, $p < 0.001$) compared to Cryo ablation. However, more adjunctive non-PV ablation was performed in the vHPSD group (33% vs 1.9%, $p < 0.001$) with overall greater procedure duration (121 ± 39 min vs 95 ± 20, $p < 0.001$). This result was unchanged after excluding cases with adjunctive non-PV ablation (110 ± 35 vs 95 ± 20 min, $p = 0.024$).

SDD rates were similar between the groups (61% with vHPSD vs 67% with Cryo, $p = 0.49$).

The usage of intravenous sedation and analgesia during the prospective study is summarised in Table 3. Patients undergoing vHPSD ablation needed higher doses of fentanyl than their Cryo counterparts (158 ± 49 mcg vs 131 ± 60 mcg, $p = 0.02$), received similar doses of midazolam, but had less usage of paracetamol (80% vs 100%, $p < 0.001$). No patient in either group developed severe hypoxemia requiring administration of naloxone or flumazenil, NIV or eIT. 15/51 (29%) of vHPSD vs 11/52 (21%) of Cryo patients

Table 2 Baseline demographics and procedural data for prospective study

	vHPSD ($N = 51$)	Cryo ($N = 52$)	p value
Age (years)	59.6 ± 11.3	57.5 ± 10.5	0.32
Female, ***n*** (%)	14 (27%)	16 (31%)	0.71
Body mass index (kg/m^2)	28.1 ± 3.8	29.6 ± 4.7	0.07
Paroxysmal AF, ***n*** (%)	38 (75%)	36 (69%)	0.55
Moderate or severe LA dilatation, ***n*** (%)	16 (31%)	13 (25%)	0.47
PVI achieved in all PVs, ***n*** (%)	48 (94%)	47 (90%)	0.72
Ablation time for PVI (min)	6.4 ± 2.9	17.9 ± 5.7	< 0.001
Patients with ablation beyond PVI, ***n*** (%)	17 (33%)	1 (1.9%)	< 0.001
Fluoroscopy time (min)	7.8 ± 6.7	19.8 ± 7.3	< 0.001
Procedure duration (min)	121 ± 39	95 ± 20	< 0.001
LA dwell time (min)	96 ± 36	67 ± 17	< 0.001
Complications, ***n*** (%)	3 (5.9%)	2 (3.8%)	0.68
Same day discharge, ***n*** (%)	31 (61%)	35 (67%)	0.49

AF, atrial fibrillation; *LA*, left atrium; *PV*, pulmonary vein; *PVI*, pulmonary vein isolation; *vHPSD*, very high power short duration

Table 3 Intravenous sedative and analgesic drugs used to achieve mild conscious sedation during vHPSD and cryoablation procedures

Pharmacotherapy agent	vHPSD ($N=51$)	Cryo ($N=52$)	p value
Fentanyl (mcg)	158 ± 49	131 ± 60	0.02
Paracetamol*, ***n*** (%)	41 (80.4%)	52 (100%)	< 0.001
Midazolam (mg)	2.0 ± 2.2	1.9 ± 1.6	0.84

*Given at a dose of 1 g

required electrical cardioversion at the end of their procedure ($p=0.50$).

3.3 Prospective study — patient experience

There was a 100% response rate to the patient experience questionnaires.

The VAS data for vHPSD vs Cryo are summarised in Fig. 1. When comparing VAS scores for patients vs operators, or patients vs nurses, there were no significant differences in anxiety, neither in the vHPSD nor the Cryo cohorts. Operator VAS estimations of discomfort and pain were similar to the patient for both vHPSD and Cryo. Nurse VAS estimations of discomfort and pain were greater than the patient's (discomfort: $p=0.02$ for vHPSD, $p=0.03$ for Cryo; pain: $p=0.007$ for vHPSD, $p=0.013$ for Cryo).

Likert scale response data from patients is shown in Fig. 2. There was no overall difference between vHPSD and Cryo groups for anxiety ($p=0.70$), discomfort ($p=0.53$) or pain ($p=0.32$) relative to the patient's own expectations. 4/51 (7.8%) of the patients in the vHPSD group indicated that they were not willing to have their procedure repeated under mCS, as compared to 7/52 (13%) in the Cryo group ($p=0.63$ for overall Likert scale response, see Fig. 3).

The combined Likert scale responses for nurses, operators and patients can be found in Fig. S1 of the Supplementary Materials. When comparing Likert scale responses for patients vs operators, or patients vs nurses, there were no differences in assessments of anxiety, neither in the vHPSD nor the Cryo arms. The nurse evaluation of discomfort was significantly greater than the patients' for both vHPSD ($p=0.03$) and Cryo ($p=0.01$), concordant with the VAS data. Operator evaluation of discomfort was also greater than the patient's, but in the Cryo group only ($p=0.02$). Unlike the VAS data, the patient's evaluation of their intraprocedural pain matched the assessment of both nurses and operators.

Eleven patients in each of the vHPSD and the Cryo groups, i.e. 22/96 (23%) of valid responses had documented pain that was "worse" or "much worse" than expected. In the Cryo subgroup, only 3 of the 11 (27%) had nurses who also perceived the patient's pain as either "worse" or "much worse" than expected. In the vHPSD subgroup, 5 out of 11 (45%) had nurses who also perceived the patient's pain as either "worse" or "much worse" than expected. Interestingly, the mean dose of midazolam was lower for these 11 patients who had experienced worse pain than for those that had not, in both vHPSD (1.8 ± 1.0 mg vs 3.2 ± 2.2 mg, $p=0.005$) and Cryo (2.3 ± 0.8 mg vs 3.1 ± 1.5 mg, $p=0.017$) subgroups. The doses of fentanyl and paracetamol were not significantly different.

4 Discussion

The present multicentre study demonstrates for the first time the feasibility of vHPSD RF PVI using mild conscious sedation. In fact, our data also show that the patient experience

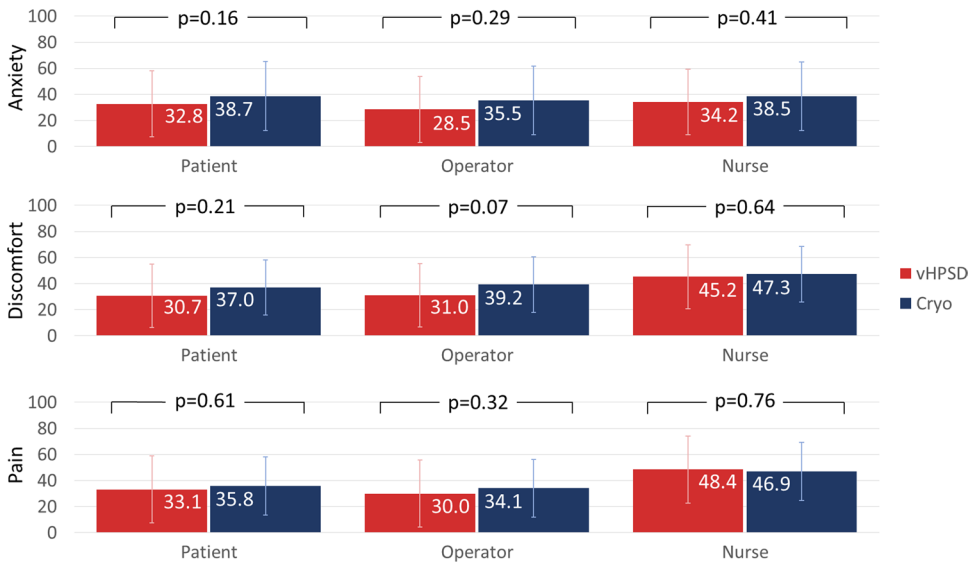

Fig. 1 Patient, operator and nurse perception of anxiety, discomfort and pain experienced during vHPSD vs Cryo ablation based on visual analogue scale assessments

Fig. 2 Patient experience of anxiety, discomfort and pain for vHPSD vs Cryo ablation based on Likert scale responses. *p* values indicate comparisons of vHPSD vs Cryo for each of the patient experience dimensions

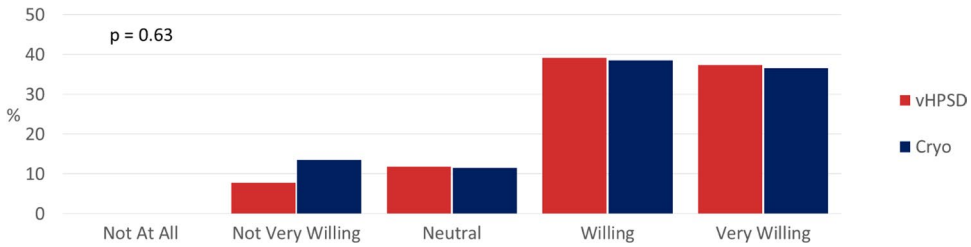

Fig. 3 Patient's willingness to undergo repeat procedure given current experience

with vHPSD ablation under mCS is very similar to that of cryoballoon ablation, a procedure that is already routinely performed using mCS. Ablation using vHPSD was associated with significantly reduced ablation time for PVI compared to sRF and Cryo ablation, and lower fluoroscopy time compared to Cryo. However, total procedure duration was greater with vHPSD than with Cryo; this is partly reflective of the additional adjunctive ablation among vHPSD patients. Equally, there is an inevitable learning curve when using new technology. SDD was achieved in similarly high proportions of patients for both vHPSD and cryoablation.

4.1 vHPSD and patient experience

Patient experience is positively associated with patient safety and clinical effectiveness, and is considered a central pillar of healthcare quality [11]. To the best of our knowledge, the present study is the first to prospectively evaluate the patient experience during vHPSD RF ablation with mild conscious sedation.

In a single centre RF AF ablation study by Ezzat and colleagues, 23% of cases were performed under GA, and 37% of AF ablation patients reported more pain than they expected [12]. By comparison, 23% of our prospective mCS study patients reported pain that was worse or much worse than expected. Within this group, it was common for both nurses and operators to underestimate pain levels. This group also received less midazolam, although other drug dosages were similar. Whilst there are likely to be multiple reasons for poor pain control, this result does remind us of the synergistic effect of benzodiazepines and opioids, as well as the need to maintain verbal and non-verbal communication to avoid under-treating patient pain.

We also demonstrate equality of patient experience between vHPSD and cryoballoon PVI. Previous work, which involved the use of deep sedation agents such as propofol, showed reduced opiate dosing for Cryo than for RF [13, 14] and less pain reactions with Cryo [14], but were confounded by the longer ablation times typically associated with standard RF ablation.

Chest pain due to cardiac nociception, the most common form of discomfort encountered during RF ablation [15], is believed to arise from the stimulation of autonomic afferent sensory endings that lie primarily within the epicardium [6]. In the context of endocardial RF ablation, such stimulation would be more dependent on the process of conductive heating which is needed for deeper lesion creation [16]. vHPSD is predicated primarily upon resistive heating [5], producing broader and shallower lesions compared to sRF [17] which in combination with the short duration of just 4 s, would be

expected to improve patient tolerance when compared with traditional RF delivery, not only from lesion to lesion, but also as a result of the much shorter overall duration of ablative therapy. This may have contributed to previous findings that painful RF lesions were more likely to have been delivered at lower powers than non-painful lesions [18].

Unlike cryoballoon therapy, point-by-point RF ablation offers the versatility of addressing substrates beyond PVI. This was utilised in only a small number of vHPSD patients when compared with sRF within our early feasibility evaluation, but had increased to a third of patients during the prospective study, indicating a relatively shallow learning curve for the use of the Q Dot Micro catheter for applications other than PVI. Furthermore, one might have anticipated that the sizeable proportion of vHPSD patients who received adjunctive ablation would negatively skew the assessment of patient experience for this group. This makes the lack of any differences in patient experience between vHPSD and Cryo particularly reassuring.

4.2 The importance of the nurse perception of patient experience

It was notable that the nurse perception of patient discomfort more often than not exceeded the patient's own perceptions. We believe that this underscores the critical role of the nursing team as a sensitive monitor and advocate of the patient during a period when the operator may be focused upon technical aspects of the case. By being more aware of the patient's needs, the nursing team are better able to respond both non-pharmacologically [19] and pharmacologically, anticipating and promoting the use of additional analgesia, both of which would have been critical determinants for all dimensions of the patient procedural experience.

4.3 Mild conscious sedation for RF ablation

Our data demonstrate that a vHPSD approach may obviate the need for GA and specialist anaesthetic support in a large majority of patients when deploying RF ablation for PVI. Although not formally assessed, we did not experience any increase in pressure on nursing staff utilising this approach.

In the era of SARS-Cov-2 in particular, this approach may contribute to reducing patient and staff exposure to aerosol-generating procedures, whilst reducing inpatient bed utilisation through SDD [10]. Previous assessments of RF ablation for AF have shown improved 1-year outcomes when using GA over mCS [20]. This has been attributed to overall catheter stability with less patient movement, affording better tissue contact. However, these studies mostly lacked CF measurements, had much longer mean procedure duration, and where reported [20], the fentanyl dose (75 ± 35 mcg) was less than half of that used in our prospective study.

In a randomised study, a 48% incidence of luminal oesophageal damage was documented using capsule endoscopy after AF ablation under GA compared with 4% in the mCS arm, thought to be related to reduced oesophageal motility and lack of patient swallowing during GA [21]. This may point towards the potential safety benefit of patient feedback during ablation with mCS that is otherwise absent under GA. By contrast, and in keeping with the aforementioned biophysics of vHPSD ablation, a recent series of 90 patients undergoing mandatory endoscopy after vHPSD ablation showed no cases of oesophageal ulceration, and just 1 small superficial erosion [22].

A limitation of vHPSD under mCS is catheter stability. Patient movement is more likely without GA, and loss of contact during vHPSD ablation can significantly affect the lesion delivered. For example, a 1-s loss of contact represents 5% of a 20-s sRF lesion, but 25% of a 4-s vHPSD lesion [23]. This can adversely affect acute outcomes [24]. In addition, until recently, the visual lesion tagging software (VisiTag) utilised on the Carto (Biosense Webster) platform was not calibrated for stability when utilising vHPSD ablation. This has been addressed in a recent software update, and our recent experience has been that this has resulted in improved first pass isolation rates.

4.4 Safety and complications

Whilst our study was not powered to assess safety, a low number of overall complications were observed without statistical difference between modalities. One patient suffered a neurological event in the vHPSD retrospective study. This was associated with a prolonged LA dwell time — specifically, PVI was challenging to achieve in this patient due to multiple connections requiring prolonged ablation. Notably, it has recently been shown that vHPSD may be associated with increased rates of charring on the catheter tip, particularly when circuit impedance is $< 100\Omega$ [24]. This requires further study.

5 Limitations

We recognise some important limitations in the current work. We did not seek to evaluate the clinical efficacy of vHPSD on follow-up compared with other established modalities beyond sRF and Cryo ablation, but instead focussed on acute procedural parameters. We did not systematically screen patients for obstructive sleep apnoea to exclude them from receiving mCS; however, this would have been expected to influence both vHPSD and Cryo groups equally, and it strengthens the real-world applicability of our findings. Our mCS protocol allowed for an anaesthetist to be available in case of need, and so our findings may not be

applicable to those settings where this specialist support is unavailable. We cannot exclude recall bias with the questionnaires, although we attempted to address this by ensuring that these were completed in a timely and consistent manner.

6 Conclusion

A vHPSD RF approach to PVI can be successfully undertaken with mild conscious sedation without compromising patient experience. This facilitates high rates of same-day discharge. Compared to cryoballoon PVI, vHPSD ablation was associated with reduced ablation times and reduced fluoroscopy exposure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10840-022-01351-5.

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Data availability Data can be provided upon reasonable request.

Declarations

Ethical approval Ethics approval was obtained from the institutional review boards. All patients provided written informed consent. The principles of the Declaration of Helsinki were followed.

Conflict of interest DG is a speaker for Bayer, BMS/Pfizer, Boehringer Ingelheim, Daiichi-Sankyo, Medtronic, Biosense Webster and Boston Scientific; proctor for Abbott and has received research grants from Medtronic, Biosense Webster and Boston Scientific. GAN has received speaker honoraria (SJM/Abbott, Biosense Webster), research fellowship funding (SJM/Abbott, Boston Scientific), support for conference attendance (Boston Scientific, Medtronic, SJM/Abbott). VL has received speaker honoraria (Biosense Webster) and research funding from the NIHR North-West Coast Scholar's programme. Other authors have no relevant disclosures to declare.

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Authors and Affiliations

Gavin Chu[1,2] · Peter Calvert[3] · Bharat Sidhu[2] · Akash Mavilakandy[2] · Ahmed Kotb[2] · Lilith Tovmassian[3] · Nikola Kozhuharov[3,4] · Cédric Biermé[3] · Nathan Denham[3] · Charlene Pius[3] · Jim O'Brien[3] · Wern Yew Ding[3] · Vishal Luther[3] · Richard L. Snowdon[3] · G. André Ng[2,5] · Dhiraj Gupta[3]

1 Lancashire Cardiac Centre, Blackpool, UK

2 Department of Cardiovascular Sciences, NIHR Leicester Biomedical Research Centre, University of Leicester, Leicester, UK

3 Liverpool Heart and Chest Hospital NHS Foundation Trust, Thomas Drive, Liverpool L14 3PE, UK

4 Department of Cardiology and Cardiovascular Research Institute Basel (CRIB), University Hospital Basel, University of Basel, Basel, Switzerland

5 Glenfield Hospital, Leicester, UK