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Conduction system pacing in France in 2022: A snapshot survey from the Working Group of Pacing and Electrophysiology of the French Society of Cardiology

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Short title: French CSP adoption snapshot survey

Tweet: CSP adoption and limitations in France in 2022

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Highlights

- CSP is an innovative approach but evidence and guidelines are lacking
- CSP has been widely adopted in France
- Important variations were apparent for implantation techniques and success criteria
- Lack of training and clinical guidelines remain limitations for wider CSP adoption

ABSTRACT

Background: Conduction system pacing (CSP) is an emerging and promising approach for physiological ventricular pacing. While data from randomized controlled trials are scarce, use of His-bundle pacing (HBP) and left bundle branch area pacing (LBBAP) has increased in France.

Aim: To perform a national snapshot survey for cardiac electrophysiologists to evaluate adoption of CSP in France.

Methods: An online survey, distributed to every senior cardiac electrophysiologist in France, was conducted in November 2022.

Results: A total of 120 electrophysiologists completed the survey. Eighty-three (69%) respondents reported experience in undertaking CSP procedures and 27 (23%) were planning to start performing CSP in the coming 2 years. The implantation techniques and criteria used for successful implantation differed significantly among operators. The most frequent indications for HBP and LBBAP were high-degree atrioventricular block with left ventricular ejection fraction (LVEF) <40% (24% and 82%, respectively) or with LVEF ≥40% (27% and 74%, respectively), and after failure of a coronary sinus left ventricular lead (27% and 71%, respectively). The limitations respondents most frequently perceived when performing HBP were bad sensing/pacing parameters (45%), increased procedure duration (41%) and risk of lead dislodgement (30%). The most frequently perceived limitations to performing LBBAP were absence of guidelines or consensus (31%), lack of medical training (23%) and increased procedure duration (23%).

Conclusions: Our national survey-based study supports wide adoption of CSP in France. CSP is currently used as a second-line approach for both antibradycardia and resynchronization indications, with important variations regarding implantation techniques and criteria for measuring success.

1. Abbreviations

AV	atrioventricular
CIED	cardiac implantable electronic device
CRT	cardiac resynchronization therapy
CSP	conduction system pacing
EHRA	European Heart Rhythm Association
ESC	European Society of Cardiology
HBP	His-bundle pacing
LBBAP	left bundle branch area pacing

LVEF left ventricular ejection fraction

Keywords:

Conduction system pacing

Cardiac resynchronization therapy

Left bundle branch area pacing

His bundle pacing

Survey

2. Introduction

Conduction system pacing (CSP) is an emerging and promising approach for physiological ventricular pacing aimed at preserving or restoring His-Purkinje conduction and left ventricular synchrony. Since the first description in humans of direct and permanent His-bundle pacing (HBP) [1] and left bundle branch area pacing (LBBAP) [2-4], clinical evidence based on major cardiovascular events from randomized controlled trials are still lacking. In the past few months, dedicated CSP material has been provided to high-volume academic centres and has become widely available in numerous centres in France. The 2021 European Society of Cardiology (ESC) guidelines on cardiac pacing and resynchronization therapy provided low-level recommendations for HBP indications (e.g. after failure of coronary sinus left ventricular lead implantation), but LBBAP was not mentioned, whereas it has become the main CSP technique used in clinical practice [5-10]. Two international CSP surveys were recently published but provided only limited data on CSP practice in France, especially in non-academic and private centres [11, 12].

We performed a national snapshot survey on CSP indications, implantation techniques and perceived limitations in centres with or without experience in those techniques.

3. Methods

An online survey comprising 21 multiple choice questions was conducted in November 2022, and was supported by the Working Group of Pacing and Electrophysiology of the French Society of Cardiology. The survey was published and shared via various media (social media platforms and

onsite industrial technical support) with all French centres performing cardiac pacing. Respondents were categorized as group 1 (who perform CSP in routine clinical practice), group 2 (who do not currently perform CSP but intend to start within the next 2 years), and group 3 (who do not perform CSP and do not project to start within the next 2 years). National yearly consumer product data of the only available CSP-dedicated lead (3830 lead, Medtronic, France) were analysed.

3.1. Statistical analysis

Data are presented as mean \pm standard deviation or number (percentage). Analyses were performed using Excel 2022 (Microsoft, USA).

4. Results

4.1. Characteristics of respondents and centres

A total of 120 electrophysiologists from 101 centres completed the online survey in November 2022. Characteristics of respondents and centres are illustrated in Fig. 1. Respondents were most often experienced in using cardiac device implanters (82/120, 68% with >5 years' experience in cardiac implantable electronic device [CIED] implantation as a first operator), working either in private, public academic or public non-academic centres. Of the 101 centres, 65 (65%) had a CIED implantation volume of between 100 and 500 per year. The mean number of cardiac device implanters was 3.3 ± 1.5 .

As illustrated in Fig. 2, 83 respondents (69%, group 1) had experience in CSP procedures (LBBAP only in 62/120 [52%], HBP only in 2/120 [1.6%] and both LBBAP and HBP in 19/120 [16%]). Among the remaining 37 (31%) respondents without CSP experience, 27 (73%) were planning to start CSP within 2 years (group 2) and 10 (27%) were not (group 3). In the 19 respondents with both LBBAP and HBP experience, the ratio of LBBAP:HBP was 95/5% in 12, 75/25% in 5, 50/50% in 1 and 25/75% in 1.

4.2. Characteristics of CSP procedures

Preferred first-line venous access for CSP lead implantation was subclavian for 45% of respondents, cephalic for 43% and axillary vein for 12%. Regarding HBP procedures, 94% of respondents declared using fixed-curve sheath (vs deflectable sheath) and 62% declared using

lumen-less leads (vs stylet-driven leads). An electrophysiological system with intracardiac recording analysis was used by 74% of respondents, with the remaining 26% using only the device programmer and a 12-lead electrocardiogram (25 mm/s recording). Regarding LBBAP procedures, all respondents declared using a fixed-curve sheath (vs deflectable sheath) and 69% declared using lumen-less leads (vs stylet-driven leads). A 12-lead surface electrocardiogram (100 mm/s recording) was used by 80% of respondents, in association with an electrophysiological system with intracardiac recording analysis by 59% of respondents. LBBAP lead positioning was performed using His-bundle in 68% of respondents and/or tricuspid ring as a marker in 52%. An additional iodine injection was declared by 7.4% of respondents. The V1 nadir notching (i.e. W pattern in lead V1 during pacing or mechanical premature ventricular contractions) was declared as a sign of appropriate initial position by 68% of respondents. None of the respondents declared using an electroanatomical mapping system during CSP procedures.

A successful HBP procedure was defined according to the following criteria: paced QRS duration <120 ms (100%), HBP threshold <2 V/1 ms (81%), His-bundle potential recording by the CSP lead (81%) and His-bundle current of injury (19% of respondents). A successful LBBAP procedure was defined according to the following criteria: R-wave peak time in V6 <80–90 ms (70% of respondents), terminal R/r wave in V1 (65%), paced QRS duration <120 ms (52%), V6–V1 interpeak interval >40 ms (47%), fixation beats (46%) and left-bundle or fascicular potential recording by the CSP lead (19%).

4.3. Indications

Regarding antibradycardia indications, CSP was declared as a first-line approach in most (i.e. >50%) procedures by 18% of respondents. Regarding resynchronization indications, CSP was declared as a first-line approach in most (i.e. >50%) procedures for 14% of respondents.

Current indications for CSP declared by respondents are illustrated in Fig. 3. In every indication evaluated, LBBAP was deemed by respondents to be more appropriate than HBP. The most frequent indications for HBP in clinical practice were high-degree atrioventricular (AV) block with left ventricular ejection fraction (LVEF) $\geq 40\%$ (27%), after failure of a coronary sinus left ventricular lead (27%) and high-degree AV block with LVEF <40% (24% of respondents). The most frequent

indications for LBBAP in clinical practice were high-degree AV block with LVEF <40% (82%) or with LVEF \geq 40% (74%), and after failure of a coronary sinus left ventricular lead (71%).

4.4. *Perceived limitations of CSP*

Perceived limitations to performing CSP in France in 2022 are illustrated in Fig. 4. The most frequent perceived limitations to performing HBP were poor sensing/pacing parameters (45%), increased procedure duration (41%) and risk of lead dislodgement (30%). The most frequent perceived limitations to performing LBBAP were absence of guidelines or consensus (31%), lack of medical training (23%) and increased procedure duration (23%).

Regarding group 1 (experienced operators), the most frequent perceived limitation to performing HBP was poor pacing/sensing parameters (51%), and the most frequent perceived limitation to performing LBBAP was the absence of scientific guidelines (36%). Regarding Groups 2 and 3 (inexperienced operators), the most frequent perceived limitation to performing HBP and LBBAP was lack of medical training (group 2: 48% and 56%, respectively; group 3: 70% and 60%, respectively).

4.5. *National consumer product data*

National consumer product data and regional proportion of centres using the Medtronic 3830 (Medtronic, Minneapolis, USA) lead are illustrated in Fig. 5. Among 312 centres, 31% used the Medtronic 3830 lead, with a maximum of 53% in Normandy and a minimum of 12% in Bourgogne Franche-Comté.

5. Discussion

CSP is an emerging alternative to conventional right and/or biventricular pacing, with dedicated tools (leads and sheaths) widely available in France, but hard clinical evidence to guide their use is still lacking. The main findings of this national snapshot survey can be summarized as follows: (1) from a large, representative sample of French cardiac implanters, CSP has already become established among cardiac pacing techniques used in routine practice; these data are corroborated by the exponential sales growth of the CSP-dedicated lead; (2) LBBAP was clearly preferred over HBP; (3) important variations were reported regarding implantation techniques and

success criteria among participating centres; (4) LBBAP was considered an alternative to both biventricular pacing after failure of coronary sinus lead implantation and right ventricular pacing in patients with high-degree AV block (regardless of LVEF); (5) among CSP-inexperienced cardiac implanters, lack of technical training was the main limitation to further expanding use of CSP. In contrast, the absence of CSP in the current guidelines was considered the main limitation for CSP-experienced cardiac implanters.

Our study provides a comprehensive analysis of CSP adoption in a national European territory, considering indications, implantation techniques, procedural criteria, perceived limitations and consumer product data. Considering data from 120 respondents from 101 centres in France, approximately two-thirds of respondents declared performing CSP implantation in clinical routine. These findings are supported by an exponential rise in sales of the only CSP-specific lead (Medtronic 3830 lead), as we found a nearly 100% growth between 2021 and 2022 sales. Our data are also supported by two recent surveys. From a survey performed in early 2021 in 140 public academic centres on 5 continents, Perino *et al.* found that 91% of centres declared implanting CSP leads [11]. However, this rate may be overestimated, as a recent European survey, performed in April 2022, reported that 64% of 184 respondents declared experience in CSP (mostly highly-experienced operators from public academic centres, from 31 countries) [12]. Our study, with a balanced profile of academic and non-academic centres and of public and private centres, may provide a more accurate snapshot of CSP adoption in late 2022, even though voluntary survey-related biases may still be the source of overestimation.

Our study supports a clear paradigm shift in CSP practice, LBBAP becoming the preferred technique over HBP. Since the first description of permanent and direct HBP in humans, theoretical indications have emerged either for antibradycardia or for resynchronization purposes. However, HBP adoption has been limited by numerous procedure-related and operator-related considerations [1, 10-13]. In our study, poor sensing/pacing parameters, increased procedure duration, theoretical risk of lead dislodgement and lack of technical training are the main reasons for refraining from the use of HBP. This finding is supported by the overall low percentages (<30%) of respondents considering HBP as a good pacing technique in the proposed clinical scenarios. Since the first description of LBBAP by Huang *et al.* in 2017 [2], reported HBP practice has declined: in our study reflecting late 2022, HBP-only practice was declared by 1.6% of respondents versus 4.9% in early 2022 [12] and up

to 30% in early 2021 [11]. In contrast, LBBAP-only practice was declared by 52% of our respondents versus 12% in early 2022 [12] and 1.6% in early 2021 [11].

Our study found important variations in CSP implantation techniques. First-line subclavian venous access for CSP was declared by approximately half of respondents, even though subclavian access is a predictor of complications, especially pneumothorax and pacemaker/defibrillator lead failure [14]. Consequently, in the recent ESC guidelines, cephalic or axillary access should be considered as first-line venous access for pacemaker lead implantation [5]. Our data could be explained by the short length of CSP delivery sheaths and the reduced manoeuvrability of the sheath from a cephalic venous access, which may limit the ability to reach the target zone. There is a definite need for longer delivery sheaths to allow CSP from cephalic (or axillary) access, although the risk of pneumothorax in the MELOS registry remained within the normal range (0.55%) [7]. The long-term effects of subclavian venous access on a CSP lead are currently unknown.

In our study, important variations were also reported regarding procedural criteria for successful implantation, especially for LBBAP. Paced QRS duration <120 ms was declared a good criterion for measuring success during HBP for all respondents, whereas it was considered important for 52% of respondents in the case of LBBAP. This is in line with the data from MELOS Registry, in which the mean paced QRS duration was approximately 140 ms during LBBAP [7]. Moreover, and in accordance with the later registry, our study underlines the multiparametric approach to validate LBBAP using the following criteria: QRS morphology transition during screwing and during the threshold test, R-wave peak time in V6 <80–90 ms, terminal R/r wave in V1, V6–V1 interpeak interval >40 ms, fixation “screw” beats and left-bundle or fascicular potential recording by the CSP lead. Finally, even though most operators declared using the lumen-less lead (Medtronic 3830), approximately one-third of respondents declared using a stylet-driven leads to perform CSP. This approach has proven feasible and safe in clinical routine [7, 15], but the choice between lumen-less and stylet-driven leads regarding patient characteristics but also regarding mid- and long-term outcomes require investigation in dedicated studies.

Although our study supports wide adoption of CSP in France, only 14% of respondents declared using CSP as a first-line approach for antibradycardia and 18% for resynchronization indications. These are higher than previously reported by Perino *et al.* [11], but still far from the anticipated applications, which were reported as high as 93% for both antibradycardia and

resynchronization indications in a recent European Heart Rhythm Association (EHRA) survey [12]. These high expectations, especially regarding LBBAP, are supported by electrophysiological evidence confirming that CSP can overcome the deleterious effects of right ventricular pacing and can even correct proximal blocks in the conduction system [3, 4, 6, 16]. Even though functional, echocardiographic and biological endpoints tend to suppose that LBBAP may be at least non-inferior to conventional biventricular pacing, clinical data focusing on hard outcomes such as hospitalization rate for heart failure or cardiovascular death derived from randomized controlled trials are lacking. While this wide gap between actual and expected indications needs to be filled by high-quality evidence, an expert consensus or addendum to the current ESC guidelines is needed in the meantime to guide clinical practice.

Approximately one-third of respondents in our survey had no experience in CSP. In this group, the main perceived limitation to performing CSP was lack of technical training, which is in line with the recent EHRA survey [12]. In a registry collecting data from 14 high-volume European centres, Jastrzebski *et al.* found a gradual learning curve for LBBAP, with the steepest part before the first 100 cases [7]. During this initial learning phase, an improvement of LBBAP electrophysiological criteria was noted (mostly paced QRS duration and R-wave peak time in V6). However, the implantation success rate reached 92% for antibradycardia and 82% for resynchronization indications. CSP requires specific training for both operators and paramedical staff to create a dedicated environment (recording system, electrical connections, etc.), with the use of specific material (sheath, lead) and to gain extensive knowledge of the success criteria. Altogether, these data highlight the importance of academic teaching, but also training centres for the development of CSP activity.

5.1. Study limitations

Our study is subject to limitations inherent to a voluntary survey-based design. The main such limitation may be overestimation of CSP adoption in France. We found a 69% rate of CSP adoption among respondents, inconsistent with a lower mean utilization rate of the Medtronic 3830 lead of only 31% on the national territory. Even though, our adoption rate is similar to that reported in the recent EHRA survey [12], which may suffer from the same limitations. However, while selection bias may explain this discrepancy and lead to overestimation of CSP adoption in our study, it is noteworthy that the Medtronic 3830 lead is not the only lead used for CSP. In our work, consumer product data were

not available for the Abbott, Biotronik and Boston Scientific leads, which are not CSP-specific, but were still used by approximately one-third of CSP-experienced respondents. Altogether, an overestimation of CSP adoption is likely in our study, but probably with a minimum effect.

Although our questionnaire was of short duration (6 min), favouring a high participation rate, our study remains inexhaustive. However, considering the total number of CEID implanting centres in France (312, source: Medtronic France), we managed to gather data from approximately 30% of French centres. Importantly, our study is the largest country-based analysis to date, as the recent EHRA survey on CSP had only 5.4 respondents per country (184 respondents for 34 countries) [12].

6. Conclusions

Our national survey-based study supports wide adoption of CSP and especially LBBAP among French CIED implanters, mostly as a second-line approach for both antibradycardia and resynchronization indications, with important variations regarding implantation techniques and success criteria. Future expectations are focused on technical training and clinical evidence-based guidelines derived from randomized controlled trials (Central illustration).

Conflict of interest

PO received consulting fees from Abbott, Biotronik, Boston Scientific and Medtronic.

FA received consulting fees and speaker honoraria from Microport CRM, Boston Scientific and Medtronic.

PD received honoraria and grants from Abbott, Boston Scientific, Medtronic, Microport CRM.

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Figure legends

Fig. 1. Characteristics of respondents ($n = 120$) and centres ($n = 101$). A) Respondents' CIED implantation experience (years); B) Centres' CIED implantation volume (per year); C) Type of centre; D) Number of electrophysiologists per centre. CIED: cardiac implantable electronic device.

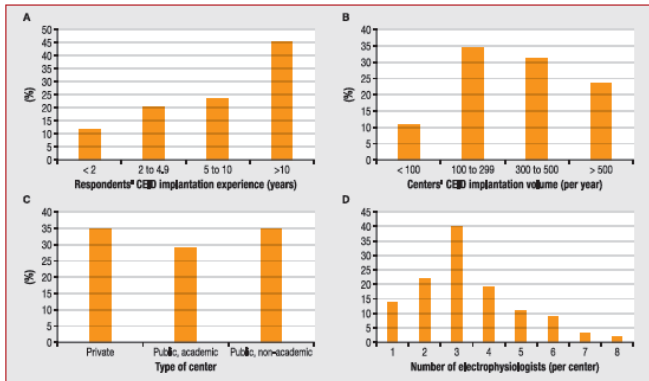


Fig. 2. Type of CSP experience declared by respondents ($n = 120$). CSP: conduction system pacing; HBP: His-bundle pacing; LBBAP: left bundle branch area pacing.

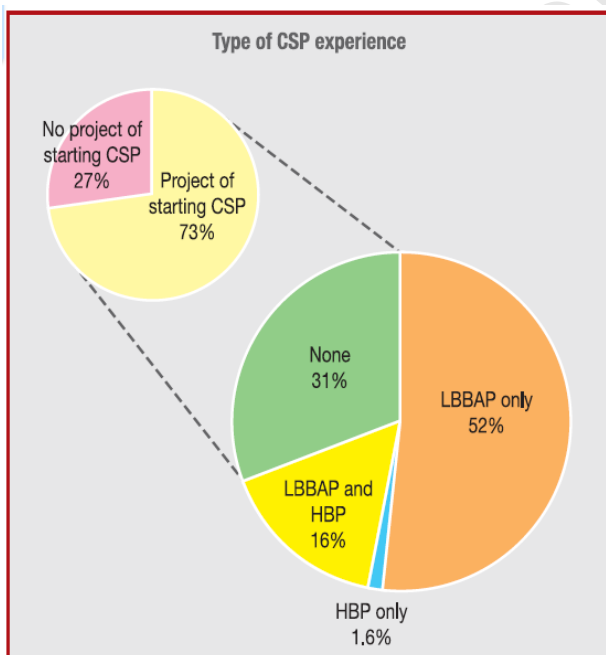


Fig. 3. Current indications for CSP in clinical practice, according to respondents. High-degree AV block indications includes “pace and ablate” strategy for AF. AF: atrial fibrillation; AV: atrioventricular; CS: coronary sinus; CSP: conduction system pacing; HBP: His-bundle pacing; HF: heart failure; LBBB: left bundle branch block; LBBAP: left bundle branch area pacing; LV: left ventricular; LVEF: left ventricular ejection fraction; RV: right ventricular; SR: sinus rhythm.

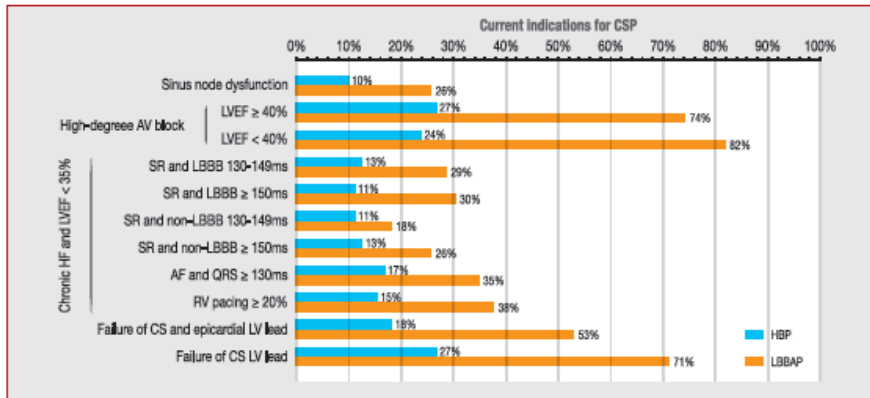


Fig. 4. Perceived limitations of CSP, according to respondents. CSP: conduction system pacing; EP: electrophysiology; HBP: His-bundle pacing; LBBAP: left bundle branch area pacing.

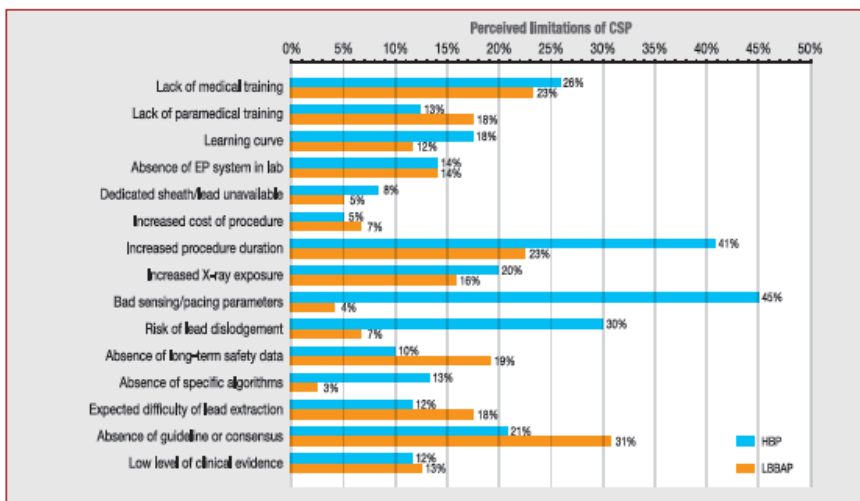
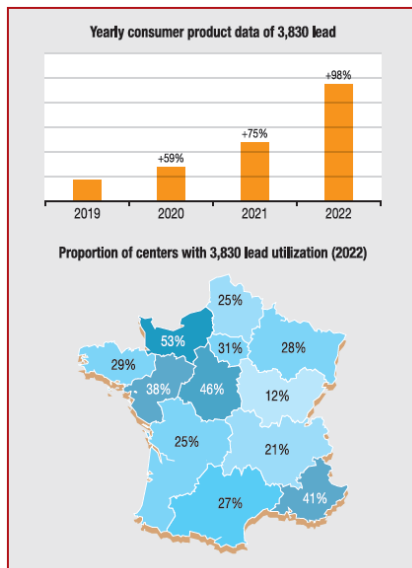


Fig. 5. (A) Yearly consumer product data for the Medtronic 3830 lead (in percentage of increase compared with previous year); and (B) proportion of centres reporting use of the Medtronic 3830 lead in 2022 (January to November).



Centra illustration. Snapshot survey of conduction system pacing in France in 2022. AV: atrioventricular; CSP: conduction system pacing.

