

Small bowel capsule endoscopy and deep enteroscopy procedure load in France: a nationwide population-based study over 7 years



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ABSTRACT

Background and study aims Capsule endoscopy (CE) is a diagnostic tool mainly used to explore the small bowel (SB), whereas device-assisted enteroscopy (DAE) is preferred for therapeutics. We aimed to describe the procedure load of SB endoscopy in France from 2015 to 2021.

Patients and methods Using the French national health data system and the French national hospital discharge database, we identified all SBCEs and DAEs reported between January 2015 and December 2021. Information on DAEs was crosschecked with data on purchase or maintenance from manufacturers. Centers and procedures were described by type, year, type of practice, and according to the 13 French administrative regions in the mainland and in those overseas.

Results A total of 151,096 SBCEs and 6,802 for DAEs were considered over the study period. SBCE service was offered in all regions, in both public and private settings, and the case load increased from 18,956 to 24,183 (+27.6%). The number of DAEs decreased nationwide, from 1,030 to 932 (−9.5%). Eighty-seven percent of all DAEs were performed in public university hospitals. Retrograde route varied between 18.8% and 22.8% of all DAEs yearly. The number of centers offering DAE varied from 0 to 5, over regions and years. DAE caseloads increased in five regions but ended, decreased or the procedure was not yet used in the nine remaining regions.

Conclusions SB endoscopy in France is marked by a 22-fold unbalanced procedure load in CE (nationwide coverage) and in DAE (absent in some regions). This gap has widened over the years from 2015 to 2021.

Introduction

Thin and long, positioned between the stomach and the colon, and a long distance from mouth or anus, the small bowel (SB) has long been poorly accessible to physicians. Previously, radio-

logical imaging was limited to SB follow-through. Since then, SB cross-sectional imaging (computed tomography scan, magnetic resonance imaging [MRI]), with or without enteroclysis, has been made available, allowing more precise but still indirect investigations. At the start of the century, the advent of capsule

endoscopy (CE) allowed direct visualization of the SB in patients with suspected small bowel bleeding (SSBB), suspected Crohn's disease, and other conditions [1], and more recently, artificial intelligence is being used to speed up the reading time for CE [2]. In parallel to CE, push and then device-assisted deep enteroscopy (DE) was developed; during these invasive and labor-intensive procedures, specifically-trained operators gain access to lesions in the SB, manipulating overtubes, balloons (single or double) or spirals (possibly motorized) in patients under general anesthesia [3]. Given that CE is non-invasive and offers direct visualization, it is preferred to cross-sectional imaging for diagnosis (but these can be combined), whereas indications for device-assisted enteroscopy (DAE) are restricted to challenging diagnoses requiring biopsies and to direct endoscopic treatments such as hemostasis, polypectomy, and dilatations. Little is currently known about SB CE and DAE procedure volumes at national levels, and whether these volumes would meet clinical needs in large populations. Therefore, we aimed to describe the availability of SB endoscopy (CE and DAE) in France from 2015 to 2021.

Patients and methods

Data source

This study was conducted using the French national health data system (Système National des Données de Santé, SNDS), which is a database that includes comprehensive individual medical information for 99% of the population living in France (approximately 67 million people) since 2006 [4]. The database contains data about all outpatient procedures reimbursed by the national health insurance system, including medication and physician visits. We also extracted data from the French national hospital discharge database (Programme de Médicalisation des Systèmes d'Information, PMSI) that comprises all procedures performed during hospital stays (including one-day clinics) in both public and private institutions (but does not include those performed in medical offices outside of institutions). All SB CE (French medical classification for clinical procedures, HGQD002) and DAE (anterograde enteroscopy [HGQE003], retrograde enteroscopy [HGQE005], combined anterograde and retrograde route enteroscopy [HGQE001], hemostasis during anterograde enteroscopy [HGSE001 or HGSE002], polypectomy during anterograde enteroscopy [HGFE003 or HGFE004], hemostasis during retrograde enteroscopy [HGSE003 or HGSE004], polypectomy during retrograde enteroscopy [HGFE001 or HGFE002]) were extracted from these databases [5]; per-operative enteroscopy (HGQE004) was not taken into account. Dilatations of ileal stenosis (HGAE001) were excluded from data collection because most procedures are performed during colonoscopy (or rectoscopy in patients with subtotal colectomy), and more rarely during enteroscopies. Enteroscopy-assisted endoscopic retrograde cholangiopancreatography were also excluded.

For DAE specifically, we crosschecked data with that of enteroscope manufacturers in France. Only data from centers equipped and/or with maintenance contracts between January 2012 to December 2021 with Fujifilm (Tokyo, Japan) double-

balloon compatible enteroscopes (EN-450T5, EN-580T), with Olympus (Tokyo, Japan) single-balloon enteroscopes (SIF-180), or with Olympus motorized spiral enteroscopes (PSF-1) were included in the study. Other centers were excluded, as they possibly used codes for enteroscopy inappropriately, and/or performed push, but not device-assisted, enteroscopy. Of note, data were analyzed per procedure, although some patients may have combined (CE then DAE) or repeated procedures (multiple CE and/or DAE, in the same year or over years).

We identified all procedures performed in France between January 2015 and December 2021. The numbers of SB endoscopy centers and procedures were described by year, type of procedure (SB CE, diagnostic DAE, therapeutic DAE, "anterograde" or "retrograde" or "combined anterograde and retrograde" DAE), type of practice (public vs private), and area (according to the 13 French administrative regions in the mainland [Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Bretagne, Centre-Val de Loire, Corse, Grand Est, Hauts-de-France, Ile-de-France, Normandie, Nouvelle-Aquitaine, Occitanie, Pays de la Loire, Provence-Alpes-Côte d'Azur], and to overseas regions [Outre-Mer]). These numbers were given in relation to the number of inhabitants per region (according to the yearly national census [6]).

Ethics

Because the information used in the study was related to only procedure codes, informed consent was not required.

Statistical analysis

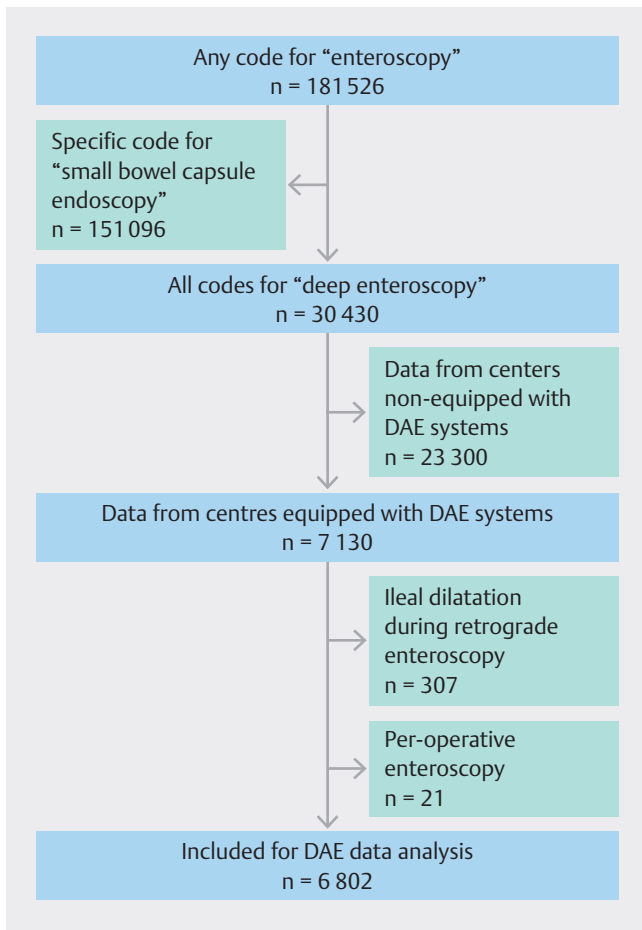
Descriptive analysis (numbers and proportions) was performed during the study period using Microsoft Excel (Microsoft, Redmond, Washington, United States).

Results

A total of 181,526 enteroscopy procedures were identified over the study period, including 151,096 specific SB CE procedures. After exclusion of centers not equipped with DAE systems (according to manufacturer's data, $n = 23,300$), and procedures that may not require DAE systems (ileal dilatation during retrograde enteroscopy, $n = 307$; per-operative enteroscopy, $n = 21$), there were 6,802 DAE procedures included (► **Fig. 1**).

Small bowel capsule endoscopy (SB CE) procedure load

Nationwide, the total number of SBCEs increased from 18,956 in 2015 to 24,183 in 2021 (+27.6%; ► **Fig. 2**). The majority (58.9%) of SBCEs in the 2015 to 2021 period were performed in public institutions. The number of medical institutions in which SBCEs were performed varied from 757 in 2015, up to 828 in 2017, and to 796 in 2019 (+5.2%), and then dropped to 701 in 2020 and 710 in 2021 (mainly due to the disengagement of 90 public institutions in 2020; Supplementary Figure 1, supplementary material). The proportion of private institutions offering SBCEs increased over the study period from 22.6% in 2015 to 33.0% in 2021.

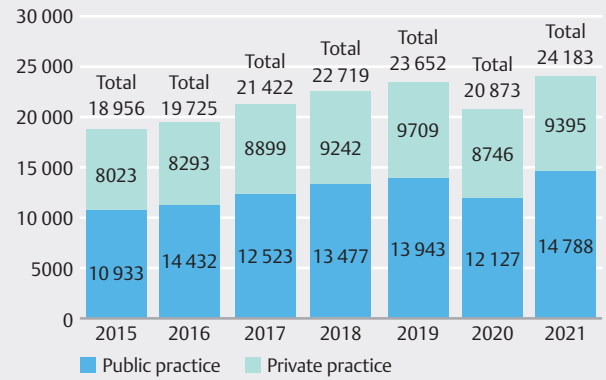


► **Fig. 1** Flowchart. Extraction and selection of small bowel capsule endoscopy and device-assisted enteroscopy (DAE) procedures from the French national hospital discharge database and from the French national health data system (Système National des Données de Santé, [5]).

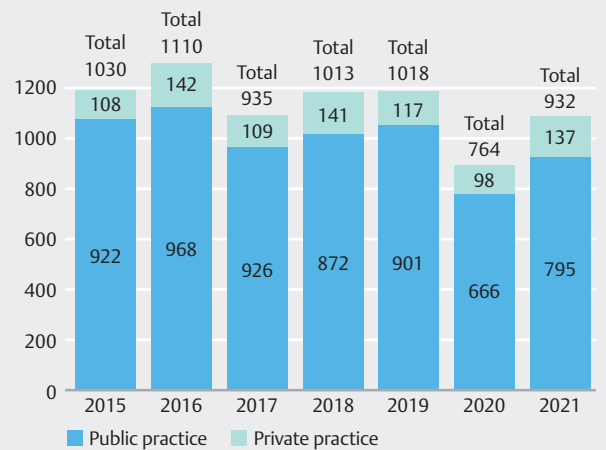
At the regional level, the total number of SBCEs performed increased between 2015 and 2021 in all regions except Centre-Val de Loire (−6.7%) and Corse (−14.7%). Most regions experienced a drop in the number of SBCEs performed in 2020 compared to 2019, except in Hauts-de-France (+0.6%), in Pays de la Loire (+3.3%), and Overseas (where it markedly increased by +11.4% in 2020 with respect to 2019, but by a small absolute number, before falling in 2021). Corse was the only region where SBCEs were consistently more frequently performed in private practice than in public settings over the study period, but a similar pattern was observed in Pays de la Loire from 2016 to 2021 (Table 1, supplementary material). Related to the number of inhabitants (according to 2021 census [6]), SBCE availability varied in 2021 from 142 per million overseas (and 214 per million in Centre-Val de Loire in the mainland) to 504 per million in Hauts-de-France.

Device-assisted enteroscopy procedure load

Nationwide, the total number of DAEs decreased from 1030 in 2015 to 932 in 2021 (−9.5%), with a reduction to 764 cases in 2020 (► **Fig. 3**). The number of medical facilities where DAE



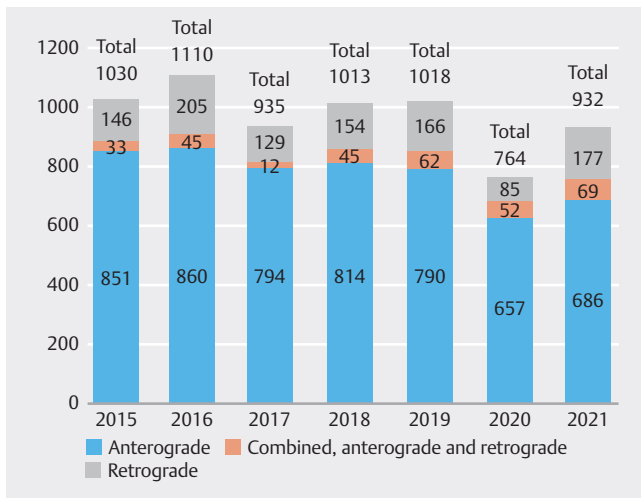
► **Fig. 2** Number of small bowel capsule endoscopy procedures performed in France each year from 2015 to 2021 according to the type of practice (public or private).



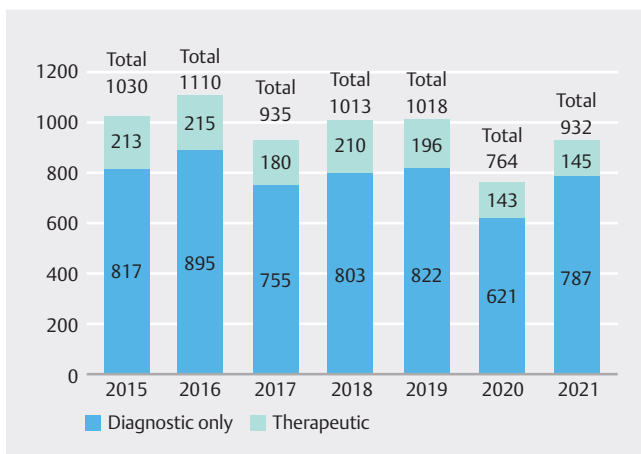
► **Fig. 3** Number of device-assisted enteroscopies performed in France from 2015 to 2021, according to the year and type of practice (public or private).

were performed (23 to 26 centers) varied slightly over the study years (Table 2, supplementary material). University hospitals provided 5,950 (87.5%) of all DAEs (n=6,802) over the study period. The numbers (and proportions) of DAEs coded as retrograde (only, or associated with anterograde) DAE varied from 179 (18.8%) to 246 (22.8%) over the study years, performed in eight to 14 centers (► **Fig. 4**). The numbers (and proportions) of therapeutic DAEs (whatever anterograde or retrograde) varied from 145 (15.6%) to 210 (20.7%) over the study period (► **Fig. 5**).

At the regional level, marked differences were noted (► **Fig. 6**). The number of centers offering DAE varied from none to five, among the regions and the years of the study period. Two regions (Centre-Val de Loire, Corse) did not offer any DAE service over the study period. Two regions (Normandie, Outre-Mer) started offering DAE after 2015, but they were still low-volume centers in 2021 (19 and 21 procedures, respectively). Among the 10 of 14 regions offering DAE in 2015, one stopped



► **Fig. 4** Number of device-assisted enteroscopies performed in France each year from 2015 to 2021 according to introduction route (anterograde, combined, or retrograde)



► **Fig. 5** Number of device-assisted enteroscopies performed in France each year from 2015 to 2021 according to the type of procedure (diagnostic only or therapeutic)

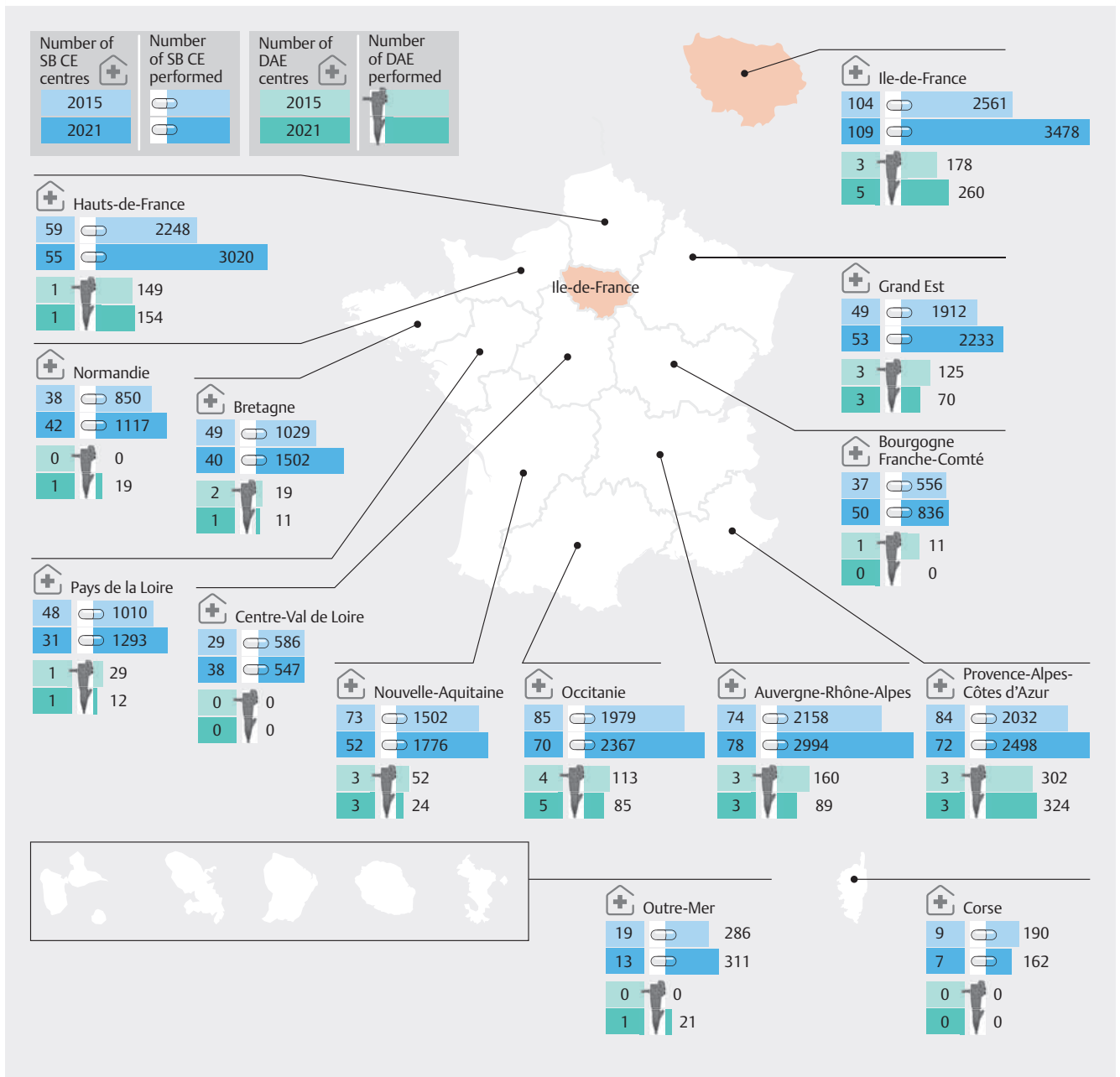
in 2020 (Bourgogne-Franche-Comté), six decreased (Auvergne-Rhône-Alpes -44.4% , Bretagne -42.1% , Grand Est -44.0% , Nouvelle-Aquitaine -53.8% , Occitanie -24.8% , Pays de la Loire -58.6%), and three increased the number of procedures (Hauts-de-France $+3.4\%$, Ile-de-France $+46.1\%$, Provence-Alpes-Côte d'Azur $+7.3\%$) from 2015 to 2021 (Table 2, supplementary material). In 2021, 22 of 24 centers (91.6%) offering DAE services were university hospitals, one was a private institution affiliated with a university hospital, and one was a non-affiliated private center. All regions had DAE activity in 2019, but Nouvelle-Aquitaine and Occitanie experienced a reduction in DAE case load in 2020. Related to the number of inhabitants (according to 2021 census [6]), the DAE case load varied from none (in 3 regions) to 36.5 procedures per million (in Provence-Alpes-Côte d'Azur) in 2021.

Discussion

This study shows that SBCE procedure load markedly increased from 2015 to 2021 in France (by more than a quarter). The number of medical institutions offering CE slightly increased from 2015 to 2019; in 2020, many public institutions disengaged (likely because of the COVID-19 pandemic). The proportions of the 24,134 SBCEs examinations performed in 2021 were slightly unbalanced between public (61.1%) and private settings (38.9%). Over the same period, service in DAE had not started, had ceased or had decreased in most (nine of 14) French administrative regions. In 2021, three regions had no DAE service and two regions (Ile-de-France and Provence-Alpes-Côte d'Azur) accounted for 584 (62.7%) of the 932 DAEs performed nationwide. A vast majority of DAEs (over 90%) in France were performed in university hospitals. Overall, from 2015 to 2021, the number of SBCEs frankly increased across the country, and in both public and private practice, whereas DAE procedure load decreased by 9.5% and was unbalanced (unequal regional offer, mostly relying on public, university hospitals).

The present study used the French national health data system [4], compiling comprehensive data from all coded SB enteroscopies in France. However, whereas SBCE has a very specific code that makes the data collection herein robust, data collection for DAE was less reliable because some procedures can be performed with non-specific endoscopes or in patients with modified anatomy, and are assimilated to deep enteroscopies. In an attempt to focus on DAE, we included only enteroscopy centers equipped (and/or with a maintenance contract) with single or double-balloon enteroscopes 3 years before data collection (i. e. since 2012), or more recently with motorized spiral enteroscopes, and we excluded peroperative enteroscopies and ileal dilatations (possibly performed with other endoscopes). These choices may have influenced the estimation of the number of DAEs performed, possibly underestimating them by excluding some procedures but possibly overestimating them as some procedures with colonoscopes or push enteroscopes in centers equipped with DAE systems may have been coded as enteroscopy; we can only acknowledge a potential bias here. The small (roughly 20%) proportion of DAEs listed as "therapeutic" is very surprising (when the procedure is mainly indicated for treatment), which also questions the validity of the data collected. We can only hypothesize that the specific codes for hemostasis and resections associated with DAE were overlooked or misused by physicians. However, the external validity of the data collected on the overall number of DAEs is consolidated by the 25.0% reduction in 2020 (most likely due to the COVID-19 pandemic) compared to 2019, which is similar to that observed for colonoscopy in France (roughly 250,000 fewer than the usual 1,400,000 yearly colonoscopies in France, -17.8%) [7, 8].

Previous data on SB endoscopy volumes are scarce. The United Kingdom and France have a similar number of inhabitants (65 and 66 million, respectively, in 2015), making comparison worthwhile. In 2012, McAlindon et al. published the results of a web-based survey of SB practice throughout the UK [9]. Of



► **Fig. 6** Number of small bowel capsule endoscopy (SB CE) and device-assisted enteroscopy (DAE) centers and procedures in the 13 mainland French administrative regions, and Overseas (Outre-Mer), in 2015 and in 2021.

334 UK sites with gastroenterology units identified in the British Society of Gastroenterology database, 187 were hospital-based, of which 84 (45%) offered SBCE services. Non-hospital-based data (if any) were not provided in this study. While procedure load had increased over the years, hospital-based cases had reached 8,430 SBCE procedures in 2010, all over the country in the UK (with unequal distribution according to regions, as observed in France). As for volume, in direct comparison (likely increased in both countries over time), our first record was made 5 years later with 10,933 SB capsule procedures performed in 586 public centers (and 8,023 in 151 private centers) in France in 2015. In 2010, 15 UK centers offered spiral and/or

double-balloon (to be compared to 24 in France in 2015). An Italian nationwide web-based survey on quality performance measures provides data from 2014 to 2018 (while the Italian population was 61 million in 2015) [10]. Eighty-four centers from 17 (of 20) Italian administrative regions provided workload data, but it is not known how many centers did not participate. From these partial data, we can merely conclude that the number of centers and procedures increased in Italy up to at least 84 and 3,899 in 2018, respectively, (to be compared to 789 centers, and 22,719 procedures in France in 2018). No data on DAE were available from the Italian initiative. Overall, web-based, self-reported procedure loads estimated from

quality surveys in other countries are incomplete, making comparisons poorly appropriate. Conversely, the main strength of our study is to provide comprehensive nationwide data on SB endoscopy procedure loads, over a long period of time, based on the French national health data system for outpatients, and on the French national hospital discharge database for inpatients (including 1-day clinics), for both public and private institutions. We must acknowledge, however, that 1% of the French population is not covered by the SNDS, that medical offices outside of institutions are not covered by the PMSI (but capsules and DAE are rarely performed in this setting), and that data on intraoperative procedures were not available. Because these limitations and volumes are minimal, we believe that the big picture provided by our data is valid. In addition, we were not able to access individual data to study the distribution of indications for SBCEs and DAEs over time, across regions and according to European Society for Gastrointestinal Endoscopy (ESGE) recommendations.

SBCE service is in essence easy to set up for gastroenterologists, and quick and easy to perform for patients. The present study found that the technology has spread all over the country, in both public and private practice, since the technology was launched in 2000, and the momentum persisted until 2019. Despite the fact that numerous public institutions stopped performing SBCE in 2020 (and did not resume in 2021), the procedure was less impacted by the COVID-19 pandemic (12.7% decrease in 2020, compared to 2019) than other, more invasive endoscopic procedures (suggested to be -17.8% for colonoscopy) [7]. SBCE's non-invasive nature has been used in other settings when anaesthesiologic resources were stretched during the COVID-19 pandemic [11, 12]. This is in contrast to the results for DAE, which seem to be the exact opposite of CE, including the frequency of this complex and costly procedure, use of fragile hardware, a frequent requirement for maintenance fees, extensive training for physicians, and a lot of resources for long and risky procedures [13] under general anesthesia, DAE procedure load dropped by 25% in 2020, most likely due to the lack of resources during the COVID-19 pandemic.

The most striking figures in this study are first, the vast difference (22-fold) in the number of SBCE procedures ($n = 151,096$) compared to the number of DAE procedures ($n = 6,802$), and second, the decoupling of the changes over time in SBCE (+27.6%) and DAE (-9.5%) case loads, in France over the study period. In addition, SBCE is performed throughout the territory, in tens of public and private institutions on the mainland, whereas DAE procedures were concentrated almost exclusively (> 90%) in university hospitals, mostly (62.7%) in the two regions where medical resources are dense (Ile-de-France and Provence-Alpes-Côte d'Azur were the only regions in France with 200 specialists or more for 100,000 inhabitants in 2021) [14]. One may hypothesize that the selection of patients for SBCE is getting loose (thus explaining the increasing number of CEs performed, nationwide), whereas the selection for DAE remains strict. However, considering a worst-case scenario in which half (12,000) of the 24,000 SBCEs in France in 2021 were indicated for SSBB (where the literature suggests that it is up to two-thirds of indications [1, 15]), with a 33% di-

agnostic yield only, whereas the ESGE suggests a 55% to 62% yield for this indication [16]), one should speculate that there are at least 4,000 indications for dedicated therapeutic endoscopy, i.e. mostly deep enteroscopies. Even though only half of cases would require DAE (because some lesions may be accessible to push enteroscopy with a colonoscope, for instance), one can expect 2,000 procedures every year (and this scenario does not even take into account other indications, with or without need for prior SBCE). Overall, with roughly 1,000 procedures performed every year, the number of DAEs performed in France seems far to meet the current need. The expert team from Sheffield (UK) suggests that the needed ratio between SBCE and DAE volumes is around 12 to 1 [17]. Even taking into account some likely bias regarding misused or overlooked codes for DAE, whereas the unique code for SBCE can be considered robust and reliable, the offer of SB endoscopies seems very unbalanced. This experience is shared by the Italian RAVE study group. The investigators noted that fewer than 40% of centers offering SBCE services were performing DAE procedures, this with high heterogeneity according to regions (as seen in France) [10]. Indeed, in France, most DAE operators approached with the numbers found in our study confirmed that DAE is competing with many other (possibly more profitable) procedures, and that they are often facing endoscope shortage and increased costs due to breakage or preventive maintenance, and that it is really challenging to meet the current demand for DAE procedures (unpublished data). These findings raise questions about the rational use of DAE, with possible solutions to increase the current offer, aiming to approach SB diseases better and faster when optical diagnosis and sampling are necessary (suspicious tumors, ulcerations or stenosis for example), to avoid surgery (including perioperative enteroscopy) when a non-invasive alternative option exists (SSBB and polyps, noticeably), and to reduce delays and costs of DAE (wherever there is a strong indication for it but it is not available at the institution or in the vicinity). There was a hope that spiral motorized enteroscopy, made commercially available in France in 2022, would change the paradigm because this technology offered new possibilities (set up and procedure time, length of SB explored) [18]. However, it was withdrawn worldwide in mid-2023 due to safety concerns. An option would now be to concentrate DAE procedures in a limited number of expert, fully-equipped centers. This would call for a significant change in the current French healthcare organization and for incentives for such centers to be developed. In addition, the recent, strong recommendation, based on high-quality evidence, from the ESGE to perform DAE within the first 48 to 72 hours after an overt SSBB favors expanding – rather than shrinking – DAE availability all over the French territory.

The current limited offer of DAE care in France also calls into question the availability of DAE training (and therefore, future care). The ESGE states that training in SBCE should be structured with a minimum of 30 SBCE readings, but training in DAE requires first competency in bidirectional endoscopy and in SBCE reading, then a minimum of 75 procedures, including 35 retrograde DAEs, with at least 50% therapeutic procedures [19]. In an environment in which DAE procedures are scarce

and not available nationwide, it is even more challenging to ensure competency in DAE.

Conclusions

In conclusion, SB endoscopy procedure load in France from 2015 to 2021 is marked by unbalanced offer in CE (nationwide coverage, with increasing volumes) and in DAE (decreasing or stopping in many regions, and absent for years in others). French endoscopy opinion leaders, medical societies and health administration should strongly consider the causes and consequences of DAE shortcomings in terms of healthcare as the highest priority, but also regarding training and research.

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Conflict of Interest

Jean-Claude Buzzi: no conflict of interest Xavier Dray: Speaker for MSD, Pfizer, Medtronic, Fujifilm, Norgine and Sandoz; consultant for Norgine and Provepharm; co-founder of and shareholder in Augmented Endoscopy. Co-founder and President of the international Capsule endoscopy REsearch (iCARE) group. Vincent Quentin: no conflict of interest Jean-Christophe Saurin: consultant for Medtronic and Provepharm

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