Journal of Arrhythmia 33 (2017) 139–143

Contents lists available at ScienceDirect

Journal of Arrhythmia

journal homepage: www.elsevier.com/locate/joa

Original Article

Automatic atrial capture device control in real-life practice: A multicenter experience

Massimo Giammaria, MD[a,*], Gianluca Quirino, MD[b], Mariangela Alberio, MD[c], Umberto Parravicini, MD[d], Eliana Cipolla, B.Eng.[e], Guido Rossetti, MD[f], Antonio Ruocco, MD[g], Gaetano Senatore, MD[h,i], Francesco Rametta, MD[j,k], Paolo Pistelli, MD[i]

[a] Cardiology, Maria Vittoria Hospital, Turin, Italy
[b] Cardiology, Annunziata Hospital, Cosenza, Italy
[c] Cardiology, Valduce Hospital, Como, Italy
[d] Cardiology, SS Trinità Hospital, Borgomanero, Italy
[e] St. Jude Medical, Milan, Italy
[f] S.Croce e Carle Hospital, Cuneo, Italy
[g] Cardiology, Cardarelli Hospital, Naples, Italy
[h] Cardiology Department, Ciriè Hospital, Ciriè, Italy
[i] Cardiology, Ivrea Hospital, Ivrea, Italy
[j] Cardiology, S.Andrea Hospital, Vercelli, Italy
[k] Cardiology, SS Pietro e Paolo Hospital, Borgosesia, Italy

ARTICLE INFO

Article history:
Received 1 March 2016
Received in revised form
27 May 2016
Accepted 6 June 2016
Available online 11 July 2016

Keywords:
Pacing
Automaticity
ICD
Pacemaker
Algorithm

ABSTRACT

Background: Device-based fully automatic pacing capture detection is useful in clinical practice and important in the era of remote care management.

The main objective of this study was to verify the effectiveness of the new ACAP Confirm® algorithm in managing atrial capture in the medium term in comparison with early post-implantation testing.

Methods: Data were collected from 318 patients (66% male; mean age, 73 ± 10 years); 237 of these patients underwent device implantation and 81 box changes in 31 Italian hospitals. Atrial threshold measurements were taken manually and automatically at different pulse widths before discharge and during follow-up (7 ± 2 months) examination.

Results: The algorithm worked as expected in 73% of cases, considering all performed tests. The success rate was 65% and 88% pre-discharge and during follow-up examination ($p < 0.001$), respectively, in patients who had undergone implantation. We did not detect any difference in the performance of the algorithm as a result of the type of atrial lead used. The success rate was 70% during pre-discharge testing in patients undergoing device replacement.

Considering all examination types, manual and automatic measurements yielded threshold values of 1.07 ± 0.47 V and 1.03 ± 0.47 V at 0.2-ms pulse duration ($p=0.37$); 0.66 ± 0.37 V and 0.67 ± 0.36 V at 0.4 ms ($p=0.42$); and 0.5 ± 0.28 V and 0.5 ± 0.29 V at 1 ms ($p=0.32$).

Conclusions: The results show that the algorithm works before discharge, and its reliability increases over the medium term. The algorithm also proved accurate in detecting the atrial threshold automatically. The possibility of activating it does not seem to be influenced by the lead type used, but by the time from implantation.

1. Introduction

The development of a fully automatic pacing system [1,2] is becoming increasingly important in today's remote-control era and is driven by the need to both improve patient safety and ensure pacing therapy. Device-based capture detection enables stimulation parameters to be continually adjusted in the ambulatory setting. This allows narrower safety margins to be used and prolongs the life of the device. Many of the follow-up tasks of the pacemaker and

Abbreviations: ICD, implantable cardioverter defibrillator; AV, atrial–ventricular; PM, pacemaker; CRT, cardiac resynchronization therapy; SD, standard deviation; SJM, St. Jude Medical

* Correspondence to: Maria Vittoria Hospital, Via Cibrario 72, Turin, Italy.
E-mail address: stent.icd@gmail.com.(M. Giammaria)

http://dx.doi.org/10.1016/j.joa.2016.06.002

implantable cardioverter defibrillator (ICD) are performed routinely and reported automatically by the device itself on the first programmer screen (fast-path). These tasks include measuring battery voltage, lead impedance, and sensed electrogram amplitude. Automatic programming adjustments for rate response, mode switching, and atrial–ventricular (AV) interval adaptation are commonplace [3–6]. These data are useful for both in-clinical and remote follow up. This capability was first described by Funke [7] in 1972. Currently, various pacemakers are able to detect ventricular capture automatically, a feature that has yielded benefits [8,9].

Furthermore, software-based solutions for pacing the cardiac chamber of interest with the lowest feasible energy and good safety margin can increase the life of the device.

Both surface and endocardial atrial signals have low amplitude and can be difficult to process because they are difficult to distinguish from signals originating from other sources. However, the availability of remote-control systems that allow the home management of patients with implantable devices has prompted researchers to develop more reliable algorithms for the automatic management of atrial capture.

The methods used for this purpose are, substantially, the analyses of atrial potentials, evoked atrial potentials [10], and ventricular rhythm in cases of stable spontaneous AV conduction [11].

Recently, St. Jude Medical (SJM) has proposed an updated version of its algorithm of atrial capture without changing the name (ACAP Confirm®). The aim of the present multicenter study was to verify the reliability of this new algorithm.

2. Materials and methods

2.1. Objective

The main objective of this study was to verify the effectiveness of the new ACAP Confirm® algorithm in managing atrial capture both in new implants and in patients undergoing device replacements. Effectiveness was defined as the number (%) of patients in whom ACAP Confirm® could be activated successfully by means of the in-clinic automatic threshold test, which means that the ACAP Confirm® is recommended by the device at the end of the test, and a threshold has been identified.

The secondary objectives were (1) to investigate the relationship with pulse width (performed by considering the percentage of activations recorded by the ACAP Confirm® Merlin PCS programmer at the end of the test run) and (2) to check the clinical equivalence of automatic and manual threshold test results.

2.2. Patient population

Data from 318 patients were retrospectively collected in 31 Italian hospitals. Data were collected in accordance with institutional guidelines on ethics. Patients underwent their first implantation or device replacement with a St Jude Medical device (PM, ICD, CRT-P, CRT-D: list of devices in appendix A) installed with ACAP Confirm® algorithm features between May 2011 and March 2012. Zephyr DR pacemakers were excluded because they were equipped with the first version of the algorithm, which had yielded unsatisfactory results [12]. Data from the first routine ambulatory follow-up examination (7 ± 2 months [range, 2–12 months]) were also collected from first-time device recipients.

2.3. Methods

In cases of new implants, data were collected after the implantation procedure and during follow-up examination; in cases of device replacement, data were collected from the box-change procedure before discharge only. Atrial capture thresholds were measured in automatic and manual modes with different pulse durations (0.2, 0.4, and 1.0 ms). If the algorithm could not return a threshold measurement, the reason was documented, and an “intention-to-treat” approach was adopted (the first attempt result was considered, although the result could easily be overcome by a second attempt, e.g., fusion could be prevented by increasing the threshold test rate).

The new version of ACAP Confirm® uses the morphology of the evoked response to determine capture versus non-capture by using a correlation score that compares the waveform shape independently from the absolute amplitude. This morphology template is stored during loss of capture and is not visible. The template is created before *each* threshold search both in-clinic and out-of-clinic. The threshold test will automatically be performed if ACAP Confirm® is recommended. Moreover, ACAP Confirm® out-of-clinic testing could be programmed every 8 or 24 h.

2.4. Statistical analysis

Categorical variables describing the patient population are expressed as absolute numbers and percentages, whereas continuous variables are shown as means (with standard deviations [SD]) or medians (with quartiles) for continuous variables. Non-continuous variables were compared by using Fisher's exact test. Normally distributed, continuous variables were compared by using two-sample t test for independent variables or paired t test for paired data. Non-parametric Wilcoxon signed rank (for paired data) tests were used for non-normally distributed variables. All P values were two sided, and a P value of < 0.05 indicates statistical significance.

Table 1
Atrial leads: manufacturer and models.

Brand	Number and frequency (%)	Models (*N* patients)
Boston Scientific	3 (1%)	Fineline 2 4480
Biotronik	3 (1%)	PX53JBP
Ela-Medical	3 (1%)	Stelid 2
Medtronic	33 (10%)	5568 (1) 5076 (2) 4076-active (1) 5554 (4) 4574 (21) 4592-passive (3) N/A (1)
St. Jude Medical	269 (84%)	1488-active (1) 1688-active (2) 1782-active (2) 1882-active (19) 1888-active (12) 1420-passive (1) 1421T-passive (1) 1474-passive (4) 1642-passive (42) 1944-passive (176) N/A (8)
Sorin	1 (0.3%)	58JB
Vitatron	3 (1%)	ICM09JB (2) IMD49JB (1)
Not available	3 (1%)	

3. Results

3.1. Patient demographics

A total of 318 patients were enrolled in the registry between May 2011 and March 2012. Of these patients, 237 underwent implantation of a new device and 81 device replacements.

A total of 183 patients underwent follow-up examination at 7 ± 2 months. In the remaining cases [54], 12%, 2%, 36%, 2%, and 48% of patients had missing auto threshold capture test results at follow up, died, dropped out owing to atrial fibrillation (AF), had dislodged atrial lead, and underwent follow-up examination in another center or were lost to follow up, respectively.

The contribution of each center varied, and enrollment ranged from 3 to 34 patients per center (median, 10; IQR, 6.5–15).

The cohort was 66% male, and age ranged from 43 to 91 years.

3.2. Implanted leads and devices

Bipolar atrial leads from eight manufacturers were implanted (Table 1); 83% of leads were of passive fixation. The most common lead location was the right atrial appendage (97.0%). The other locations were the atrial lateral free wall (2.0%) and septum (1.0%). Atrial leads were newly implanted in 237 patients (75%). The remainder had chronic atrial leads (5 ± 2.4 years).

The devices implanted were dual-chamber pacemakers (50%), biventricular pacemakers (2%), dual-chamber implantable defibrillators (17%), and biventricular defibrillators (31%).

3.3. ACAP reliability

The ACAP Confirm® algorithm returned a measured atrial threshold in 211/318 (66%) patients, particularly, in 154/237 (65%) of first-implant patients and in 57/81 (71%) of device replacements.

The success rate was 88% (161/183) during follow-up examination in the newly implanted devices; this was significantly higher than the implant time rate (65%; $p < 0.001$). In the newly implanted patients, 86% of tests were performed on the day of implantation/right after the procedure, 10% on the day following implantation, and the rest (4%) within 6 days. In the same population, automatic capture tests at early post-implantation and at the first follow-up ambulatory visit had the same performance at the two evaluations (either activable or not) in 73% of cases; the algorithm performed well on follow up, but not on implantation (only in 4% of the patients did the algorithm perform well on implantation but not on follow-up) in 23% of cases, suggesting that inflammation/maturation lead processes might play a role in the success of the algorithm.

With regard to new implants, no significant difference in reliability was found among leads from different manufacturers, either post-implantation (132/201 [66%] SJM vs. 19/30 [64%] non-SJM; $p = 0.83$) or on follow-up examination (137/157 [87%] SJM vs. 21/22 [95%] non-SJM; $p = 0.47$).

In contrast, the algorithm was activated in 46/55 (84%) devices equipped with SJM leads against 11/24 (46%) devices with non-SJM leads ($p = 0.002$) in cases of device replacements.

Tests were performed at different impulse widths (0.2, 0.4, and 1 ms; Fig. 1); the algorithm could be activated in 327/485 (67%), 342/487 (70%), and 201/484 (42%) cases at 0.2 ms, 0.4 ms, and 1 ms, respectively.

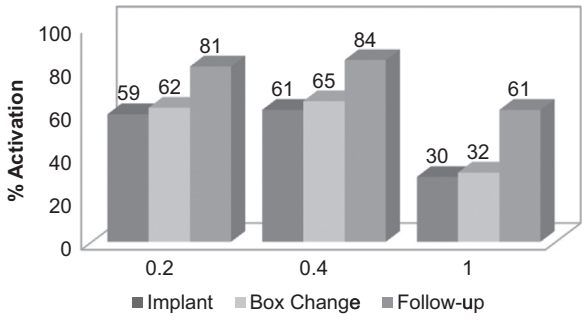

Fig. 1. ACAP Confirm® activation rate at different pulse widths and examination times.

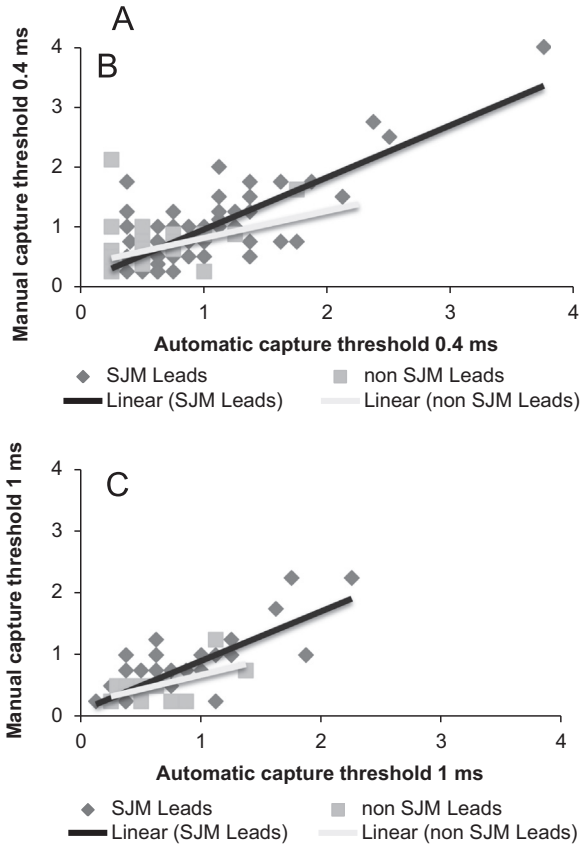

Fig. 2. Correlation between manual and automatic (ACAP Confirm®) thresholds at different pulse widths: (A) 0.2-ms pulse width $r = 0.82$, $p < 0.01$ (SJM leads) and $r = 0.75$, $p < 0.01$ (non-SJM leads); (B) 0.4-ms pulse width $r = 0.82$, $p < 0.01$ (SJM leads) and $r = 0.38$, $p < 0.01$ (non-SJM leads); (C) 1-ms pulse width $r = 0.79$, $p < 0.01$ (SJM leads) and $r = 0.59$, $p < 0.01$ (non-SJM leads).

Table 2
Reasons why ACAP Confirm® was not recommended.

	Algorithm Code	*N* patients *n* = 51/120 (%)
Not recommended for safety margin	1	2 (4%)
	2	1 (2%)
	3	17 (33%)
	4	13 (25%)
	5	4 (8%)
	6	0
Unable to perform test	Fusion or competitive heart rate	14 (27%)

The algorithm code appears on the programmer screen after the test if the algorithm is not recommended. The manufacturer provided information that number 3 was a template matching failure (loss of capture and capture snapshots are similar) criteria. This is fusion failure; the test should be run again at a higher base rate.
Other codes are gain or template matching failure, which are difficult to solve or interpret.

A secondary objective was to demonstrate that automatically measured ACAP Confirm® values were equivalent to manual threshold measurements in the acute and chronic phases.

During in-office visits, ACAP Confirm® was tested by comparing manual and automatic threshold measurements in 323, 339, and 197 tests at 0.2-ms, 0.4-ms, and 1-ms pulse widths, respectively; Wilcoxon signed-rank test revealed no statistically significant difference at any pulse width.

Considering all examination types, manual and automatic measurements yielded threshold values of 1.07 ± 0.47 V and 1.03 ± 0.47 V at 0.2-ms pulse duration ($p=0.37$); 0.66 ± 0.37 V and 0.67 ± 0.36 V at 0.4 ms ($p=0.42$); and 0.5 ± 0.28 V and 0.5 ± 0.29 V at 1-ms ($p=0.32$).

Manual and automatic measurements are presented in Fig. 2, which shows the results of Pearson correlation analysis. Overall, the correlation between automatic and manual threshold tests was greatest at 0.2-ms pulse width ($r=0.82$), whereas the analysis of atrial leads by manufacturer (SJM vs. non-SJM) revealed a better correlation at all pulse widths (Fig. 2) with leads produced by the same device manufacturer (Fig. 2, correlation $r=0.82$ for both 0.2 and 0.4 ms).

The reasons for ACAP Confirm® threshold test failure, aside from competitive heart rate, PAC (Premature Atrial Contraction)/PVC(Premature Ventricular Contraction), or noise that can temporarily impair successful ACAP Confirm® testing (27%, Table 2), were documented in (51/120) patients wherein ACAP Confirm® test was not successful at the first attempt. The most common reason (number 3) was that the manufacturer declared an unsatisfactory match between atrial capture-evoked response and the template collected owing to fusion (33%, Table 2). Competitive heart rate, PAC/PVC, or noise, and "test canceled owing to safety margins not met (3)" (27%+33%) are often transient, and a new attempt could yield a positive ACAP Confirm® automatic threshold test result.

4. Discussion

This is the first report on the current ACAP Confirm® release. This study investigated the accuracy and applicability of the ACAP Confirm® algorithm in pacemakers and ICDs. The results showed that the algorithm operates as intended, and that ACAP-determined thresholds are similar to manually measured atrial thresholds. Polarization values gradually increase with pulse width as previously described by Luria [13].

Considering the correlation between manually and ACAP-determined thresholds, a better correlation overall emerged at all different pulse widths when both the device and leads were from the same manufacturer; the best correlation was seen at the lower pulse width when the leads were from different manufacturers.

One important finding is the reliability of ACAP at different pulse widths, which enables current drain to be minimized in the event of pacing threshold increase by avoiding voltage multipliers [14]. Indeed, this feature differs across manufacturers, being available only in SJM and Biotronik devices, and can enable automatic voltage/duration adjustment in the event of a threshold increase, thereby maximizing device longevity.

A previous study conducted on the old ACAP algorithm [12] found that the system was activated only in 1% of patients in the acute phase, and that this figure increased to 50% after two weeks. In contrast, the new algorithm displayed a significantly higher percentage of activation immediately after implantation in our experience. However, the system was activated in a significantly higher percentage of patients during the first follow-up examination than immediately after implantation ($p<0.001$) similar to the previous study [12].

Our experience shows that the reliability of ACAP improved in the early days after atrial lead implantation, regardless of the fixation type, and no significant difference was found among leads from different manufacturers. The activation rate was markedly higher in comparison with the older algorithm.

Older leads, particularly non-SJM leads in patients undergoing replacement, yielded a lower ACAP success rate. This was mainly due to the manufacturing process, wherein non-SJM leads were not specifically designed to achieve low polarization. This aspect is of key importance when it comes to the detection of low voltage signals, such as atrial signals.

The algorithm was seen to work better with new leads from several manufacturers than with lower polarization leads; it worked better when both the device and leads were from the same manufacturer in cases of older leads.

5. Conclusions

This study of 318 device recipients installed with ACAP Confirm® demonstrated that the algorithm is accurate and reliable over the medium term. The new version of ACAP Confirm® proved to be already operational pre-discharge, and its activation was seen to have increased further at the first follow-up examination (the time from lead positioning/acute inflammation and, lead type might play a role in this increase in cases of device replacement).

5.1. Study limitations

ACAP Confirm® measurements were limited to patients who did not have chronic or persistent AF, as this capability is available in DR and CRT devices only.

In this study, the first test was performed before discharge from the hospital after device implantation/replacement; this means that the ACAP Confirm® test was performed at the same time in all patients. We noted that measurements obtained on the day of implantation differed from those obtained after one day, although the sample was not large enough to show any statistical significance.

Finally, as this study was not a prospective randomized controlled trial, the ACAP Confirm® function was not programmed to specific settings after implantation.

Author contributions

Giammaria, Massimo: Concept/design, data analysis/interpretation, drafting article, Data.
Collection, Critical revision of article.
Quirino, Gianluca: Concept/design, drafting article, data Collection.
Alberio, Mariangela: Data collection.
Parravicini, Umberto: Data collection.
Cipolla, Eliana: Technical support, manuscript revision, result interpretation.
Rossetti, Guido: Data collection.
Ruocco, Antonio: Data collection.
Senatore, Gaetano: Data collection.
Rametta, Francesco: Data collection.
Pistelli, Paolo: Data collection.

Conflicts of interest

All authors declare no conflict of interest related to this study.

Appendix A

1. Pacemaker DR: PM 2112 Accent DR
2. Pacemaker CRT: PM 3112 Anthem
3. ICD CRT: Unify Quadra 3251-40/40Q
4. ICD CRT: Unify 3535-40
5. ICD CRT: Promote Accel 3215-40/40Q
6. ICD CRT: Promote Quadra 3239-40/40Q
7. ICD DR: Fortify ST 2235-40/40Q
8. ICD DR: Fortify 2233-40/40Q
9. ICD DR: Current Accel 2215-36/36Q.

Appendix B

Real ACAP Registry Research Group

Fabrizio Orlando, MD[1]; Maria Teresa Lucciola, MD[1]; Giorgio Tadeo, MD[2]; Giulia Filippini, MD[3]; Fabio Canavese, MD[3]; Paola Paffoni, MD[4]; Stefano Maffè, MD[4]; Antonello Vado, MD[5]; Endrj Menardi, MD[5]; Emanuela Racca, MD[5]; Ciro Mauro, MD[6]; Claudia Amellone, MD[7]; Marco Giuggia, MD[7]; Giuseppe Trapani; MD[7]; Vincenzo Magnano, MD[8]; Benedetta Bertola, MD[8]; Aldo Pinnavaia, MD[9] Francesco Mauro De Rosa, MD[10]; Antonello Talarico, MD[10]; Angelo Catalano, MD[11]; Giovanni D'Angelo, MD[11]; Domenico Sarno, MD[12]; Fabrizio Pizzetti, MD[13]; Gabriele Dell'Era, MD[13]; Pier Giuseppe De Marchi, MD[13]; Stefano Rossi, MD[14]; Marco Scaglione, MD[15]; Mimmo Caponi, MD[15]; Paolo Di Donna, MD[15]; Daniela Righi, MD[15]; Andrea Sibona, MD[16]; Francesca Bianchi, MD[16]; Stefano Grossi, MD[16]; Valerio Freggiaro, MD[17]; Vincenzo Martinelli, MD[17]; Antonio Visconti, MD[18]; Emanuela Boffa, MD[18]; Bianca Peyracchia, MD[19]; Paolo Corsetti, MD[19]; Alberto Desalvia, MD[20]; Mauro Bensoni, MD[20]; Hossin Mohammad Moballeghi, MD[20]; Roberto Mureddu, MD[21]; Rosa Coppoletta, MD[21]; Marco Piana, MD[21]; Cosimo Tolardo, MD[22]; Catia Checchinato, MD[22]; Filippo Rabajoli, MD[22]; Marcello Giudice, MD[23]; Marco Sicuro, MD[23]; Bruna Catuzzo, MD[23]; Daniela Barbieri, MD[24]; Massimo Bignotti, MD[24]; Alice Scopinaro, MD[25]; Gianfranco Pistis, MD[25]; Riccardo Massa, MD[25]; Eraldo Occhetta, MD[26], Andrea Magnani, MD[26]; Ferdinando Varbella, MD[27]; Antonio Mazza, MD[27]; Anna Ferraro, MD[27]; Giangfranco Viciglione, MD[28]; Rossano Battista, MD[29]; Valentina Conti, MD[30]; Gerardo Nigro, MD[31].

Institutions

[1]Maria Vittoria Hospital, Turin, Italy; [2]Valduce Hospital, Como, Italy; [3]Circolo Hospital, Busto Arsizio, Italy; [4]SS.Trinità Hospital, Borgomanero, Italy; [5]S. Croce e Carle Hospital, Cuneo, Italy; [6]Cardarelli Hospital, Naples, Italy; [7]Ciriè Hospital, Ciriè, Italy;[8]S.Paolo Hospital, Borgosesia, Italy; [9]Ivrea Hospital, Ivrea, Italy; [10]Annunziata Hospital, Cosenza, Italy; [11]Maria SS. Addolorata Hospital, Eboli, Italy; [12]S.Giuseppe Moscati Hospital, Aversa, Italy; [13]S.Spirito Hospital, Casale Monferrato, Italy; [14]Circolo Hospital, Saronno, Italy; [15]Cardinal Massaia Hospital, Asti, Italy; [16]Mauriziano Hospital, Turin; Italy; [17]SS. Antonia e Margherita Hospital, Tortona, Italy; [18]Monsignor Giovanni Galliano Hospital, Acqui Terme, Italy; [19]Martini Hospital, Turin, Italy; [20]S.Giovanni Bosco Hospital, Turin, Italy; [21]Imperia Hospital, Imperia, Italy; [22]S. Croce Hospital, Moncalieri, Italy; [23]Regional Hospital Aosta, Italy; [24]Circolo Hospital, Tradate, Italy; [25]SS:Antonio, Bigio, Cesare Arrigo Hospital, Alessandria, Italy; [26]Maggiore della Carità Hospital, Novara, Italy; [27]Riuniti Hospital, Rivoli, Italy; [28]Marcianise Hospital, Marcianise, Italy; [29]Piedimonte Matese Hospital, Caserta, Italy; [30]Civico Hospital, Chivasso, Italy; [31]Monaldi Hospital, Naples, Italy

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