J Interv Card Electrophysiol (2006) 15:179–183
DOI 10.1007/s10840-006-9004-x

Activity-based rate-adaptive pacemakers under hyperbaric conditions

Alexandre Trigano · Vincent Lafay · Olivier Blandeau · Samuel Levy · Bernard Gardette · Christophe Micoli

Received: 8 March 2006 / Accepted: 21 April 2006 / Published online: 10 August 2006

Abstract
Objectives The aim of this study was to test a variety of currently available activity-based rate-adaptive pacemakers under hyperbaric conditions.
Background Sports divers with pacemakers can dive under certain circumstances. The rate response of activity-sensing pacing under hyperbaric conditions has rarely been evaluated.
Materials and methods We manufactured a miniaturized hyperbaric chamber. A pacemaker inside was kept close to the corresponding telemetry wand placed on top of the chamber. An inflation device for coronary balloon angioplasty was used to create hydraulic pressure. Group I pacemakers were exposed to a 30 msw/98 fsw/4 ATA and after a 1-month waiting period to 60 msw/197 fsw-depth/7 ATA. Group II was exposed to only one dive to 60 msw. The electrogram and event marker telemetry were used to monitor the pacing stimuli and measurements were made for case distortion.
Results The baseline pacing rate did not change in 27 tests. Return to baseline was shown during 18 tests after transient sensor-driven rate. There was a sensor rate response to manual brief shaking during and following testing. A case distortion was shown in 15 of 29 tests at 60 m.
Conclusions Modern accelerometers showed no sensitivity to pressure on the pacemaker can at 30 msw/98 fsw and 60 msw/197 fsw but in some devices responded to pressure changes. There was no pacing dysfunction or suppression of the sensor response despite the high incidence of case distortion at 60 msw/197 fsw. As a general rule, diving should not be allowed at depths greater than 20 msw/65 fsw.

Keywords Rate-adaptive pacing · Activity-sensing pacemakers

Abbreviations

fsw	feet subwater
msw	meters subwater
spm	stimuli per minute
ATA	atmosphere absolute

1 Introduction

Environmental interference of activity-based rate-adaptive pacing has been well documented in experimental and clinical studies but the literature contains no data on rate-adaptive pacing under hyperbaric conditions. Only a tiny proportion of pacemaker recipients wish to dive and no clinical data are available. As mentioned by Wood and Ellenbogen "*pacemaker patients can participate in scuba diving after consultation with their cardiologist*" [8]. Diving is an activity, for which having a pacemaker can be a disqualifier, based on the potential damage to the pulse generator that hydrostatic pressures underwater can cause through compression. For diving medical committees, the pacemaker must be certified by the manufacturer as able to withstand the pressure changes involved in diving. The diver should also achieve an appropriate heart rate response

A. Trigano (✉) · O. Blandeau · S. Levy
Department of Cardiology, Centre Hospitalier Universitaire Nord,
13915 cedex 20,
Marseille, France
e-mail: alexandre.trigano@mail.ap-hm.fr

V. Lafay
Department of Sports Medicine, Hôpital Salvator,
Centre Hospitalier Universitaire,
Marseille, France

B. Gardette · C. Micoli
Comex, Centre for Hyperbaric Studies,
Marseille, France

to exercise [1]. The aim of this study was to test a variety of activity-based rate-adaptive pacemakers placed in a custom-built hyperbaric chamber.

2 Materials and methods

A miniaturized hyperbaric chamber was specifically manufactured for this study by the Centre for Hyperbaric Studies, Comex, Marseille. This chamber has an 850-ml volume, a 100-mm diameter, and a translucent cover for visual observation (Fig. 1). The pacemaker placed inside was in close proximity to the corresponding telemetry wand outside the chamber. Hydraulic pressurization was achieved with an inflation device commonly used for coronary balloon angioplasty with operating pressure up to 21 ATA. The pacemakers tested were selected from our Cardiology Department among explanted devices collected either post mortem or after reoperation for generator replacement. The pacemakers tested were commonly used models from four manufacturers (Ela, Guidant, Medtronic and St. Jude Medical). The devices eligible for the study had (1) no history of can or header trauma during and following explantation; (2) normal response at interrogation; and (3) were activity-sensing models using an accelerometer.

3 Pacing monitoring

Following interrogation, the DDDR or SSIR activity-based sensing mode was reprogrammed, with an upper rate of more than 120 spm and other rate response parameters at nominal or median values. The electrogram and event marker telemetry were used to monitor the pacing rate. All devices were interrogated following the test and again for delayed dysfunction at 1 month following the last hyperbaric test. A manual brief shaking of the device was used to show the rate increase achieved by the sensor before and following testing.

Fig. 1 The pacemaker was placed in the hyperbaric chamber, and the inflation system was connected to the chamber with the telemetry wand positioned on the cover

4 Case measurements

The thickness of each individual pacemaker model is slightly irregular, and a precise surface scanning is required to identify a can distortion provoked by testing. Pacemaker thickness was measured with an electronic slide caliper, with a margin of error of 0.05 mm. Before the test, the entire surface of the device was scanned by the caliper to measure the maximal and minimal values of the thickness, and the difference was calculated. Following the test, the case was inspected for obvious distortion and measurements were repeated. The distortion was expressed as a change in the difference after testing. A distortion $\geq$0.2 mm was considered significant. Radiography of the device with a marker fixed on a given macroscopic can deformation was used to visualize the correlation of the distortion with the components.

5 Hyperbaric testing

The hyperbaric test consisted of a pressurization phase of less than 10 s, followed by a pressure phase of 20 min. A shake test of the hyperbaric chamber was used to show if a rate increase could be achieved during the pressure phase by the device inside the chamber. After a decompression phase of less than 10 s, the device was taken out of the chamber. Two pressure levels were tested: 30 and 60 meters subwater (msw), which are, respectively, 98 and 197 feet subwater (fsw), and, respectively, equivalent to 4 and 7 ATA. For each pacemaker brand, the models eligible for the study were randomly distributed among two groups. A first set of pacemakers was used for exposure of the same models at a 30-msw depth and then a 60-msw depth, with a 1-month waiting period between the two tests, to confirm normal functioning before second testing (group I). A second set was exposed to only one dive at 60 msw (group II).

6 Statistical data

The data are presented as the mean ± standard deviation and range.

Table 1 Results at 30 msw/98 fsw and 60 msw/197 fsw (Group I)

Manufacturer	Model	Mode	Baseline rate (spm)	Transient sensor-driven rate increase at 30 msw (spm)	Transient sensor-driven rate increase at 60 msw (spm)	Distortion following testing at 60 msw (mm)
Ela	113	SSIR	65	0	0	0
	2210	SSIR	65	+12	+12	0.2
	2550	DDDR	60	0	0	0.4
Guidant	972	SSIR	60	0	+15	0.3
	1170	SSIR	60	+8	+20	0.5
	1194	SSIR	60	0	0	0.2
Medtronic	731	DDDR	60	+30	+35	0.2
	731	DDDR	70	+10	+25	0.2
	731	DDDR	60	+18	+20	0.1
	731	DDDR	80	+10	+20	0
St. Jude	5172	SSIR	65	0	0	0
	5370	DDDR	60	0	0	0
	5380	DDDR	60	0	0	0
	5330	DDDR	60	0	0	0.1
	5330	DDDR	60	0	0	0
	2525T	SSIR	60	0	0	0

A 1-month waiting period was observed between the two tests.
msw meters subwater, *fsw* feet subwater, *spm* stimuli per minute.

7 Results

A total of 45 tests were conducted, 32 in group I and 13 in group II. At baseline, all devices were functioning normally ex vivo. Monitoring of pacing stimuli during testing did not show any pacing dysfunction or reversion at the magnet rate. During pressurization, in most devices a transient deformation of the can was observable through the chamber porthole. In 27 tests at the 30 msw/98 fsw or 60 msw/197 fsw, the baseline pacing rate did not change. A transient rate increase was noticed in 18 tests. This sensor-driven rate occurred just after inflation. The rate increase from the minimal pacing rate was from 8 to 35 stimuli per minute. The pacing rate returned to the programmed lower rate at the end of the deceleration time and did not change during stable exposure (Tables 1 and 2). During the pressure phase, a rate increase after manual shaking of the chamber could be shown in all tests. No pacing dysfunction or abolition of sensor response was shown during or immediately following testing and at the time point of at least 1 month after testing. A rate increase still could be induced by direct manual shaking of all devices.

Following testing at 30 msw, thickness measurements showed no change. Following testing at 60 msw, a permanent deformation with distortion ≥0.2 mm was identified in 15 of 29 devices: 7 in group I and 8 in group II (Tables 1, 2 and 3). The mean value of the distortion in these 15 tests was 0.33 mm ± 0.19 (range 0.20–0.80). All

Table 2 Results at 60 msw/197 fsw (Group II)

Manufacturer	Model	Mode	Baseline rate (spm)	Transient sensor-driven rate increase at 60 msw (spm)	Distortion following testing (mm)
Ela	213	DDDR	65	0	0.1
	2550	DDDR	60	0	0.3
Guidant	1270	DDDR	75	+25	0.75
	1270	DDDR	60	0	0.8
Medtronic	731	DDDR	80	+20	0.2
	731	DDDR	80	+17	0
	931	DDDR	75	+10	0.1
	E2VDD01	SSIR	65	+15	0.1
St. Jude	5376	DDDR	60	0	0.3
	5376	DDDR	60	0	0.2
	5330	DDDR	60	0	0.2
	5330	DDDR	60	0	0.3
	2425T	SSIR	68	0	0

msw meters subwater, *fsw* feet subwater, *spm* stimuli per minute.

Table 3 Distortion following testing

	n-tests	Distortion following testing at 30 msw (*n*-distortions/*n*-tests)	Distortion following testing at 60 msw (*n*-distortions/*n*-tests mean value, mm(range))
Group I	32	0/16	7/16–0.28 ± 0.12 (0.2–0.5)
Group II	13	NA	8/13–0.38 ± 0.24 (0.2–0.8)
Groups I and II	45	0/16	15/29–0.33 ± 0.19 (0.2–0.8)

The data are presented as the mean ± standard deviation and range.
NA nonavailable, *msw* meters subwater, *fsw* feet subwater.

distortions were shown by the device radiography to stand at the level of the electronic module. There was no lesion or disconnection of the connector block.

8 Discussion

Earlier pacemakers were shown by Kratz in 1983 to function normally under hyperbaric conditions [2]. The depths at which individual pacemaker models were tested ranged from 10 to 60 msw in data supplied by manufacturers and mentioned by Wilmshurst in 1998 [7]. Nowadays, no specific recommendations for diving are included in the physician's manual supplied by the manufacturers. Testing protocols and results of their laboratories remain unpublished data.

There are different types of authorizations for divers-in-training, scientific or sports divers. Depth certifications to levels from 10 to 60 msw provide a mechanism to incrementally gather diving experience. Our protocol tested two commonly used limits.

Diving with compressed air is not permitted beyond a depth of 60 msw. The inflation phase appears as a "worst case scenario" in the relevance of the study to the practice of diving. The pressures achieved in the chamber were created in less than 10 s, whereas those in diving may well be much slower. The progression, repetition or duration of compressions and the postural changes occurring during real-life diving were not considered in our protocol.

The 1-month waiting period to repeat testing was arbitrary since no data exist on potential late dysfunction following exposure.

9 Pacing rate

In rate-adaptive pacemakers included in our protocol, an accelerometer is mounted on the circuit board, allowing the sensor to be mechanically insulated from the case and preventing increases in pacing rate as a result of simple pressure on the pulse generator. The transducer measures the change of velocity of a mass suspended on a frame by a spring. In some models (St. Jude Medical 2425, 2525), the accelerometer detects the movement of a magnetic ball to obviate rate acceleration caused by direct pressure on the pacemaker. Accelerometers respond to a particular range of vibration frequencies (0.5 – 4 Hz), reducing unwanted external vibrations [3]. In earlier models with a piezoelectric crystal mounted on the inside of the case, direct pressure could cause rate acceleration [6]. The accelerometer showed lower rate changes during applied direct pressure. In tests reported by Lau, a 4 kg weight applied on top of an implanted device for one minute with the patient supine, induced no pacing rate change [4]. In our study, the rate response to the manually operated inflation resulted from several factors, including case mechanical characteristics, sensor properties, rate response algorithm. This response may also be relevant to the setting parameters but our tests were not repeated for a same model with different sensor settings. Manual shaking confirmed a response to mechanical stimulation during the pressure phase and following testing but was not a specific or uniform protocol.

10 Mechanical resistance

A resin-filled pacemaker rather than a gas-filled model was proposed in earlier recommendations to ensure more reliability during diving [5]. For practical reasons, the case reversible distortion observable inside the chamber could not be quantified. It probably prevented the devices from any permanent macroscopic lesion at 30 msw testing. The testing at 30 and then 60 msw in group I demonstrated the mechanical vulnerability of the same models at the higher pressure. Testing at 60 msw in groups I and II showed variable resistance to the same pressure among different models. The location of the distortion above the electronic module confirmed the higher resistance of the part of the device that houses the battery. The long term mechanical and electronic consequences of distortion is unknown.

11 Recommendations for diving

Commonly implanted in the pre-pectoral subcutaneous tissue, the pacemaker is exposed to the same ambient

pressures as the diver. At great depths, the mechanical stress of the electronic components will compromise pacing. Recommendations for safe recreational diving in pacemaker recipients should be based on hyperbaric testing of each individual model and the depth limit for the diver has been proposed to be set at 10 m shallower than the depth rating on the pacemaker [5]. In our tests at 30 msw/97 fsw, there were no pacing dysfunction nor case distorsion. As a general rule, diving should not be allowed at depths greater than 20 msw/65 fsw. In addition, using our protocol, a specific model or specific programming settings could be examined on a case-by-case basis.

Recommendations also include that the patient achieve an appropriate rate response to exercise. Persistence of the rate response to external mechanical stimulation was shown in our study during the pressure phase and following testing but the real rate response to normal activity of implanted devices under hyperbaric conditions remains to be evaluated.

12 Study limitations

Undetectable physical deterioration and minor pacing abnormalities cannot be completely ruled out. A change in the performance of the sensor cannot be ruled out since no specific protocols were compared and no uniform shaking protocol was used. Monitoring the detection function would have required a protocol including a signal detected by the device inside the hyperbaric chamber. Physical characteristics of devices and sensor technology differ significantly among different manufacturers and models. Our results were limited to a small sample of models and settings. More prolonged exposures may have other effects.

13 Conclusion

Modern accelerometers showed no sensitivity to pressure on the pacemaker can at 30 msw/98 fsw and 60 msw/197 fsw but in some devices responded to pressure changes.

There was no pacing dysfunction or abolition of the sensor response despite the high incidence of case distortion at 60 msw/197 fsw. As a general rule, diving should not be allowed at depths greater than 20 msw/65 fsw.

References

1. Divers Alert Network. http://www.diversalertnetwork.org/medical/faq.
2. Kratz, J. M., Blackburn, J. G., Leman, R. B., & Crawford, F. (1983). Cardiac pacing under hyperbaric conditions. *Annals of Thoracic Surgery*, *36*, 66–68.
3. Lau, C. P., Stott, J., Toff, W., Zetlein, M., Ward, D., & Camm,V. J. (1988). Selective vibration sensing. *Pacing and Clin Electrophysiol*, *11*, 1299–1309.
4. Lau, C. P., Tai, Y. T., Fong, P. C., Li, J., Leung, S. K., Chung, F., et al. (1992). Cinical experience with an activity-sensing DDDR pacemaker using an accelerometer sensor. *Pacing and Clin Electrophysiol*, *15*, 334–342.
5. UK Sport diving medical committee. http://www.uksdmc.co.uk/standards.
6. Wilkoff, B., Shimokochi, D., & Schaal, S. (1987). Pacing rate increase due to application of steady external pressure on an activity sensing pacemaker (abstract). *Pacing and Clin Electrophysiol*, *10*, 423.
7. Wilmshurst, P. (1998). Cardiovascular problems in divers. *Heart*, *80*, 537–538.
8. Wood, M., & Ellenbogen, K. (2002). Cardiac pacemakers from the patient's perspective. *Circulation*, *105*, 2136–2138.