Journal of Neuroradiology (2016) 43, 37—42

Available online at ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com/en

ORIGINAL ARTICLE

PC400 volumetric coils minimize radiation, reduce procedure time and optimize packing density during endovascular treatment in medium sized cerebral aneurysms

Jérôme Berge*, Florent Gariel, Gauthier Marnat, Vincent Dousset

Neuroradiology Department, Bordeaux University Hospital, Bordeaux, France

Available online 11 December 2015

KEYWORDS
Endovascular procedures;
Intracranial aneurysm/therapy;
Embolization;
Therapeutic/instrumentation;
Embolization;
Therapeutic/methods;
Treatment outcome

Summary
Background and objectives: The Penumbra Coil 400 (PC400) is designed to improve endovascular filling for intracranial aneurysms. The aim of this retrospective, single-operator study was to compare the use of the PC400 with conventional 0.010 inch coils in procedure time, X-ray exposure and packing density.
Methods: We collected data from 31 patients with 6 to 10 mm diameter aneurysms embolized using the PC400, from May 2012 to November 2013. This group was compared with a control group of 27 patients treated with conventional 0.010 inch coils by the same operator. In both groups, clinical events, number of coils used, duration and cost of procedure, time of fluoroscopy and packing density were studied.
Results: No serious adverse events were found in either group. Asymptomatic prolapse of coil loop into the parent artery were noted in two patients. Number of coils used was 4.45/6.35 in PC400 and control groups, respectively. Duration of procedure was 29.8/49.2 minutes respectively (*P*-value = 0.0002), and time of fluoroscopy was 28/41 minutes (*P*-value = 0.0109). Total radiation was 6098/6876 cGy.cm^2 respectively. Comparison of packing densities after the first coil showed respectively 22.7%/10.6%, and after the final imaging, 53%/28.5% (*P*-values < 0.0001). Complete or near complete occlusion on follow-up at 3 months was 100% for PC400 versus 92% in the control group. Using 0.010 inch coils may result in a 56% increase in treatment cost.
Conclusion: PC400 coils save procedural time and time of fluoroscopy, are cost saving and allow dramatic improvement of packing density on final imaging.

* Corresponding author. Service de Neuroradiologie, Hôpital Pellegrin-Tripode, place Amélie-Raba-Léon, 33076 Bordeaux cedex, France. Tel.: +33 689871647; fax: +33 556795639.
E-mail address: jerome.berge@chu-bordeaux.fr (J. Berge).

http://dx.doi.org/10.1016/j.neurad.2015.10.002
0150-9861/

Introduction

Endovascular treatment has been the first-line treatment for intracranial aneurysms for two decades [1,2], thanks to safety and recanalization rate improvements, but the main concern continues to be aneurysmal recurrence on long-term follow-up [3]. Relationship between recurrence encountered in 20% of cases [4] and rebleeding has been proven and is still challenging for the treatment of aneurysms. In the meantime, many attempts to improve coil characteristics were made, with an interest in coil coating and 3D shape architecture. Packing density has also been studied since there seems to be an association between coil compaction and decrease in recanalization rate [5].

This attempt to decrease long-term recanalization is the main objective of the newly developed Penumbra coil PC400 (Penumbra Inc, Alameda, California, USA). The other objectives are to decrease time of procedure and fluoroscopy duration due to physical properties related to its 0.0200 inch diameter double helix that provides 400% more volume per unit length than conventional 0.010 inch coils. Previous reports have highlighted advantages of this recently FDA-approved coil in terms of periprocedural efficiency and also concerning cost effectiveness and packing density [6–8].

In our experience, particular focus was placed on the comparison of procedure duration, number of coils used and above all in terms of time of procedure, fluoroscopy duration and total radiation exposure for the patient. To our knowledge, this is one of the first data collections with Mascitelli [9] to quantify these safety concerns in as far as we know that procedure time is related to morbidity-mortality linked to angiographic exams and surely to endovascular therapeutic procedures [10]. We also collected packing density data obtained with the PC400 system. It was of high importance to compare densities obtained with this new volumetric coil with traditional 0.010 inch coils in a control group with comparable angiographic characteristics. Hence, we decided to focus our comparison upon patients harboring aneurysms from 6 to 10 mm in diameter and comparable aneurysmal volume.

This work is a single-operator retrospective initial experience with aneurysms of both groups treated in the same period in consecutive patients, from May 2012 to December 2013.

Materials and methods

This was a monocentric, retrospective, observational study with neither additional risk nor use of experimental device for included patients, approved by our local Institutional Review Boards/Ethics Committees (DC: 2015/16). Signed informed consent was required to analyze numerical personal data. It was conducted in a neuroradiology department in 75 patients who had been treated with the new PC400 coil since April 2012. We rapidly decided to compare data obtained with this volumetric coil to a control group to emphasize our results. The choice to focus on aneurysm main diameters between 6 and 10 mm was justified by our beginning experience and the belief that this PC400 coil with its 0.020 inch diameter addressed aneurysms over 6 mm to minimize any learning curve side effects on small aneurysms. Behavior of the larger diameter microcatheter required and possible potential wall compression were also unknown in smaller aneurysms. For aneurysms over 10 mm in diameter, endovascular treatment is prone to address larger necks and thrombosed sacs with origin of heterogeneous pathology. It was of higher importance to compare homogeneous groups and for this reason, we decided to exclude all the aneurysms treated with adjunctive devices such as remodeling balloons, stents and flow diverters and to focus on pure coiling treatment in both groups. Forty-five out of 75 patients were excluded from this study, being out of the 6–10 mm range. In patients included with multiple aneurysms, we assessed time spent to treat elected aneurysms. Thus, we included 31 subjects with aneurysms between 6 and 10 mm in the PC400 arm with no use of other 0.010 inch coils in association with the PC400. In the control group, 27 subjects were included with aneurysms treated using different brands of coils: Micrus coils (DePuy Codman/Johnson and Johnson, Warsaw, Indiana, USA), Target Therapeutics coils (Boston Therapeutics/Stryker, Kalamazoo, Michigan, USA) and Microvention coils (Terumo, Tokyo, Japan). These 27 patients were treated anteriorly to the PC400 group, consecutively in the same diameter range and by the same physician. Therefore, the two groups were not randomized but selected with exactly the same conditions in successive periods of time.

In the PC400 group, 12 aneurysms were ruptured and 19 unruptured, whereas in the control group, 14 were ruptured and 13 unruptured. In both groups, clinical events related to treatment were analyzed. Measurements included minimum/average/maximum diameter and volume for each aneurysm of each group. Measurements were evaluated on three-dimensional images. Volume was calculated with Angiocalc software (http://www.angiocalc.com), an open source calculator endorsed by all manufacturers whose coils were used in this study. Number of coils deployed was counted. Procedure duration, time of fluoroscopy and total radiation exposure were compared. Duration of procedure was limited to coiling time from the introduction of the first coil to the last coil detachment to avoid any bias related to unequal pre-coiling time and hazardous aortic and carotid catheterization. We measured packing density with Angiocalc software (after 1° coil and on the final image) in both groups. Focus on the 6–10 mm range provided optimal homogeneity of our population rather than choosing number and total length of coils used per unit volume of aneurysm [7] because these values are completely different when dealing with 3 mm or 20 mm diameter aneurysms.

Aneurysm occlusion rate on the final imaging and 3-month follow-up angiograms were graded using the Roy-Raymond scale [11] to evaluate the influence of packing density on short-term recurrence onset. We also compared cost of procedure in both groups. The angiographic review was non-blinded and achieved simultaneously by two experienced interventional neuroradiologists working in the same team. Our statistical analysis intended to compare procedure and fluoroscopy duration, total radiation and packing density between two groups using the *t*-test. Chi^2 test was used to compare post-intervention and 3-month angiographic results.