Solitaire AB Stent-Assisted Coiling of Wide-Necked Intracranial Aneurysms: Mid-term Results From the SOLARE Study

BACKGROUND: Endovascular treatment of intracranial aneurysms can be technically difficult when the neck is wide. The Solitaire AB stent (Covidien, Irvine, California), the only fully retrieved stent, assists in the coiling of wide-neck intracranial aneurysms.

OBJECTIVE: To evaluate the mid-term angiographic follow-up of wide-necked aneurysms treated with the Solitaire AB stent.

METHODS: SOLARE (SOLitaire Aneurysm Remodeling) is a consecutive, prospective study conducted in 7 European centers. A core laboratory evaluated the postoperative and mid-term (6 months ± 15 days) angiographic results by using the Raymond classification Scale. Recanalization was defined as worsening, and progressive thrombosis was defined as improvement in the Raymond scale score.

RESULTS: The mean width of the aneurysm sac was 7.5 mm, and the mean diameter of the aneurysm neck was 4.7 mm. Angiographic mid-term follow-up was obtained in 55 of 65 aneurysms (85.9%). Complete occlusion was achieved in 33 aneurysms (60%); a neck remnant was seen in 16 aneurysms (29.1%) and an aneurysm remnant in 6 aneurysms (10.9%). Of 55 aneurysms, recanalization was observed in 8 aneurysms (14.5%), and progressive thrombosis was observed in 17 aneurysms (30.9%). No bleeding or rebleeding was observed during the follow-up period.

CONCLUSION: Stent-assisted coiling of wide-necked intracranial aneurysms was found to be safe and effective with the Solitaire AB stent at 6-month follow-up. Angiographic results improve with time due to progressive thrombosis of the aneurysm.

KEY WORDS: Coiling, Intracranial aneurysm, Recurrence, Stenting

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tent-assisted coiling (SAC) has been used with increasing frequency over the past few years, particularly for addressing endovascular treatment of wide-neck intracranial aneurysms. Chalouhi et al.,1 in the largest series published to our knowledge, reported a 3% combined permanent morbidity and mortality rate after SAC of 552 aneurysms. However, these results concerned the Neuroform stent (Stryker Neurovascular, Fremont, California) and Enterprise stent (Codman, Miami, Florida). Considering the Solitaire AB stent (Covidien, Irvine, California), we recently reported the immediate clinical and anatomic posttreatment results of a consecutive prospective registry conducted in 7 European centers.2 However, the influence of the Solitaire AB stent on the angiographic outcome after endovascular treatment of intracranial aneurysms is unknown because of the lack of prospective data.

Our objective was to evaluate the mid-term anatomic results in 64 intracranial aneurysms treated with the Solitaire AB stent and included in a prospective multicenter European registry.

METHODS

SOLARE (SOLitaire Aneurysm Remodeling) Protocol and Population

The SOLARE study including patients with intracranial aneurysms treated with a self-expandable Solitaire AB stent was conducted between June 2009 and July 2010 in 7 European centers. Patients harboring intracranial aneurysms, ruptured or unruptured, arising

ABBREVIATIONS: mRS, modified Rankin Scale; SAC, stent-assisted coiling
Data Analysis

Clinical and procedural data were collected and entered via an electronic Web site by the investigator. Quality of data, exhaustivity, and consecutiveness were checked by clinical research associates at each site. Statistical analysis was independently conducted.

All reported adverse events related to the treatment were analyzed blindly by a neuroradiologist (F.T.) and are described in this series. Permanent morbidity and mortality of endovascular treatment were evaluated before and after treatment, at hospital discharge, and at 1- and 6-month follow-up. Morbidity was defined as a modified Rankin Scale (mRS) score of 2 to 5. When preoperative mRS score was greater than 1, morbidity was defined by any increase of mRS. Any modification within 30 days after endovascular treatment was designated a treatment-related death.

RESULTS

Clinical Results

Of the 64 patients (65 aneurysms) who were initially included in the registry, 1 was excluded (neck length <4 mm), and 1 missed the 6-month follow-up. Finally, 62 patients had a clinical follow-up. The 6-month clinical results are reported in Table 1. No deaths were reported during the follow-up period. Only 1 patient experienced slight worsening at 6 months, from an mRS score of 0 at baseline to a score of 1 at 6-month follow-up. The permanent 6-month morbidity rate was 0%, and the mortality rate was 0%.

Anatomic Results

According to the core laboratory evaluation, at 6 months, 4 aneurysms were not assessed (1 with no stent placed, 1 with no coils placed, 1 missed visit, 1 visit by phone only), and 6 were not successfully evaluated due to stent artifacts (magnetic resonance imaging [MRI]). Of the 65 aneurysms that were initially included in the registry, 55 had mid-term anatomic follow-up by angiography after treatment. Progressive occlusion occurred in 17 aneurysms (30.9%), and recurrence in 8 aneurysms (14.5%) (Table 2). Complete occlusion was obtained in 33 (60%) of 55 aneurysms at 6 months compared with 27 (42.1%) of 63 aneurysms in the postprocedure evaluation (Figures 1 and 2). The number of aneurysms with a residual neck remnant decreased from 25 of 64 aneurysms (39.1%) to 16 aneurysms (29.1%). Parent artery patency was seen in all aneurysms. At 6 months, all of the assessable aneurysms had stable stent placement with complete aneurysm neck coverage.

DISCUSSION

The immediate safety and efficacy of the Solitaire AB stent in the treatment of wide necked intracranial aneurysms were demonstrated and reported previously. In this study, we assessed

<table>
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<tr>
<th>Modified Rankin Scale Score</th>
<th>Pre-procedure (n = 63)</th>
<th>1-Month Follow-up (n = 63)</th>
<th>6-Month Follow-up (n = 63)</th>
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the mid-term clinical and anatomic results of Solitaire AB SAC of wide-necked intracranial aneurysms. The SOLARE study is the first prospective, consecutive, multicenter study of the Solitaire AB stent.

Description of Solitaire AB Stent and Technical Aspects

The Solitaire AB stent is used to retain coils within the aneurysm, thus reducing the risk of embolic complications from coil herniation into the parent artery. Compared with Neuroform and Enterprise stents, the Solitaire AB stent is a self-expanding nitinol device that could be completely deployed and fully retrieved at the end of the procedure. Retrievability is a unique feature of the Solitaire AB stent that allows stent repositioning or removal if desired by the treating physician. The goal of the study was to assess whether the characteristics of this device affected the benefits to the patient. Apart from retrievability, this set of characteristics cannot be individually evaluated, and their evaluation is reflected in the global results as safety and efficacy. In the SOLARE study, the stent was used but retrieved at the end of the coiling in 1 patient.

Safety of the Solitaire AB Stent

The results of SAC vary widely across different studies. In a French series of 216 aneurysms treated with stents, the rates of permanent morbidity and mortality were as high as 7.4% and 4.6%, respectively. Elsewhere, morbidity and mortality rates with SAC were found to be lower. In this series, mortality was 0%, and permanent morbidity was 0%, which confirms the safety of the Solitaire SAC for wide-necked intracranial aneurysms. In the retrospective series of 104 intracranial aneurysms

| TABLE 2. Cross-Table Results of Postprocedural Occlusion and Occlusion at 6 Months by the Core Laboratory |
|-------------------------------------------------|---------------------------------|---------------------------------|
| Postprocedure (n = 64) | 6 Months (n = 55) |
| Complete occlusion | 27 (42.1) | 33 (60.0) |
| Neck remnant | 25 (39.1) | 16 (29.1) |
| Aneurysm remnant | 12 (18.8) | 6 (10.9) |

*At the postprocedure assessment, 1 aneurysm occlusion status was not assessed because no stent was placed. At 6 months, 10 aneurysms has no follow-up: 1 with no stent placed, 2 lost to follow-up, 1 visit by phone only, and 6 due to stent artifacts.
treated with the Solitaire AB stent reported by Clajus et al., the morbidity and mortality were evaluated at 3.9% and 2.9%, respectively. These results are not different from those reported in the large series of 508 patients treated with Neuroform and Enterprise stents. In these series, the procedure-related morbidity and mortality rates were 3%.1

Mid-term Anatomic Results of Solitaire AB Stent

Despite the fact that this series includes wide-necked aneurysms, the mid-term rates of recanalization were low (14.5%). The recurrence rate in our series is largely in line with previously reported SAC series. Using Neuroform stents, Gentric et al10 reported a 9.7% rate of recurrence, whereas Maldonado et al9 reported a 14.5% rate of recurrence after Neuroform SAC of 76 aneurysms. A limitation in our series is the fact that at 6 months, 10 aneurysms were not adequately assessed by imaging according to the core laboratory, including 6 due to stent artifacts on MRI. To date, artifacts introduced by stents limit the value of MRI as a follow-up modality after SAC.12 Contrast administration also improved vessel lumen visualization.13 Conventional catheter angiography remains the gold standard. There is a need for even later follow-up to assess the rate of long-term recurrence.

Intracranial stents offer scaffolding for reconstruction of the intimal layer of the parent artery at the aneurysm neck and may also promote progressive thrombosis.5,9,10,14-16 In the retrospective series of Clajus et al9 dealing with 104 aneurysms treated with the Solitaire AB stent, 39.2% of the aneurysms revealed further occlusion. In the literature survey of Shapiro et al,13 approximately 45% of 1510 aneurysms were completely occluded at first treatment session, increasing to 61% on the median 6-month follow-up (695 patients provided imaging). Fiorella et al14 reported, in patients treated with Neuroform stent-assisted coiling, a progressive thrombosis in 52% of the cases. Piotin et al15 reported, by using Neuroform and Enterprise stents, further thrombosis in 72.6% of aneurysms with significantly fewer recurrences in the stented aneurysm group despite inclusion of larger aneurysms with lower packing densities. The final results of this series are lower than those previously reported, with progressive thrombosis of the aneurysm documented in 30.9% of cases.

Although SAC has a lower recurrence rate than conventional coiling, 40% of aneurysms were not completely occluded at 6 months in our series.17 This rate compares well with the recent review of Shapiro et al.13 To date, the predictive factors of progressive thrombosis failure are not well known. This could be related to different designs of available intracranial stents: the open-cell design of the Neuroform stent and the closed-cell design of the Enterprise and Solitaire AB stent. Open-cell design stents could, in principle, adjust better to curved and tortuous vasculature, but they may be associated with some adverse mechanistic effects, such as increased cell opening or strut prolapse.18 However, in the series of Chalouhi et al dealing with 508 patients treated with Neuroform and Enterprise stents, closed-cell stents were associated with significantly lower aneurysm recanalization rates. Thus, the closed-cell design of the Enterprise stent may more efficiently alter intra-aneurysmal hemodynamic parameters and promote saccular thrombosis.

We observed no case of in-stent stenosis during the angiographic follow-up period, comparing well with the series of Clajus et al.9 Forty-nine patients were followed for 13.6 months, and no clinically relevant in-stent stenosis was observed. Neuroform use has been associated with a 5.8% occurrence of delayed moderate or severe in-stent stenosis, 22% of which were symptomatic.16 To date, the rate of Enterprise in-stent stenosis is not well known because only initial results of Enterprise stent use in SAC was reported, and no follow-up data outside the immediate perioperative were available.7

CONCLUSION

SAC of wide-necked intracranial aneurysms was found to be safe and effective with the Solitaire AB stent at 6-month follow-up. Angiographic results improve with time due to progressive thrombosis of the aneurysm.

Disclosure

This registry was financially supported by Covidien/ev3. Dr Klisch is consultant for Covidien/ev3. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES

COMMENT

The authors present their mid-term (6 months) results of the SOLARE (SOLitaire Aneurysm REModeling) study, which consists of stent-assisted coil embolization of wide-necked intracranial aneurysms using the Solitaire AB (aneurysm bridging) stent, currently not available in the United States. This is a follow-up study to the recently published early results of the same study that involved 7 European centers. Using the Raymond classification scale, complete occlusion was achieved in 33 aneurysms (60%) as opposed to the previously reported 42.1%. Further, neck remnants decreased from 39.1% to 29.1%. Progressive occlusion occurred in 30.9%. Aneurysmal recurrence occurred in 14.5%. Only 1 patient experienced worsening (0-1) of their mRS score. The mortality rate was still zero. The authors concluded that using the Solitaire AB to coil embolize wide-necked aneurysms is safe and aneurysmal occlusion improves with time, as seen in other cases of stent-assisted coiling.

Endovascular device technology continues to advance with each new one on the market. The Solitaire AB is unique given its ability to be retrieved, repositioned, and deployed at will. This potential advantage may improve the ability and confidence of practitioners to perform stent-assisted coil embolizations, especially given that the use of this device has been shown to have a similar safety profile. What has not been shown are the long-term results with regard to aneurysm occlusion. There are still many questions that remain, especially regarding the use of antplatelets and their timing and the fact that the cell sizes of the Solitaire AB stent are larger than the both the Neuroform and Enterprise stents. Comparisons with other similar large cell size devices, eg, LVIS, remain to be seen.

Ultimately, the goal of all of these devices is to provide a useful tool that is both safe and effective when treating wide-necked aneurysms. This report indicates that the Solitaire AB is at least on that path.

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CME QUESTIONS

1. What is an advantage of stent assisted coiling of intracranial aneurysms compared to coiling alone for wide neck aneurysms?
   A. Progressive thrombosis of aneurysm remnant
   B. Decreased complication rate
   C. Decreased cost
   D. Decreased long-term aneurysm recanalization rate

2. What is the approximate recanalization rate of wide necked aneurysms treated with stent-assisted coiling?
   A. 5%
   B. 15%
   C. 25%
   D. 35%
   E. 45%

3. What is the advantage of stent retrievability in stent assisted aneurysm coiling (SAC)?
   A. Lower incidence of embolic complications
   B. Avoidance of anticoagulant medications
   C. Ability to treat wide-necked aneurysms
   D. Optimization of stent deployment
   E. Ability to treat ruptured aneurysm