**Early and mid-term outcomes following transcatheter embolisation of type 1 endoleaks: single centre experience in 25 patients.**

**Abstract**

Purpose:

To report the technical success and follow up results of transcatheter embolisation of type 1 endoleak (EL1) in 25 patients following endovascular aortic repair (EVR).

Method:

25 patients with EL1 (20 men, 5 women; mean age 80 yrs; range 64-96 yrs) underwent embolisation of abdominal EL1 (23 proximal, 2 distal endoleaks) following EVR. All patients were unsuitable for standard endovascular methods for EL1.

The average aneurysm sac size prior to embolisation was 8.2 cm (range 5.3-12.9cm). The average time between EVR and endoleak diagnosis was 685 days (range 1-4220) and from endoleak diagnosis to embolisation 27 days (range 2-94). Onyx alone or in combination with detachable coils was used for embolisation.

Results:

A total of 27 embolisation procedures were performed, 2 patients having undergone a repeat procedure. Onyx alone was used in 16 cases and Onyx and coils were used in 11 cases. Immediate technical success with complete isolation of the endoleak on completion angiography was achieved in all procedures. There were six procedural complications: 3 puncture site hematomas and 3 cases of non-target Onyx embolisation. None of the complications had long term sequelae.

During the follow-up period (average 311 days; range 1-1357), 7 patients (28%) developed endoleak recurrence; 2 had a second embolisation procedure. Of these one has had no further endoleak recurrence, the other developed a recurrent endoleak and died from sac rupture. Of the other 5 cases of endoleak recurrence, two were successfully managed by other procedures, one had a persistent endoleak despite aortic cuff placement and the other two were deemed unsuitable for further intervention. Three of the four patients with persistent endoleaks have died from sac rupture. Freedom from endoleak recurrence was %, Freedom from sac growth was x %.

Conclusion:

Transcatheter embolisation of type I endoleaks offers a safe, feasible and sustainable treatment option. Additional coil embolisation prior to Onyx injection may result in a better outcome.

**Introduction**

Type 1endoleaks (EL1) are one of the leading factors necessitating intervention following endovascular aortic repair (EVAR), reported in up to 10% of EVAR cases[1]. EL1 results from an inadequate seal at the proximal (type 1a - EL1a) or distal (type 1b- EL1b) attachment sites of the aortic endograft. The resultant communication between the high pressure aortic lumen and the peri-graft space can result in increased sac pressurisation (endotension) and sac expansion.

Treatment of EL1 is advocated because of the risk of rupture and lack of spontaneous resolution[2]. Standard treatment options for a proximal type 1 endoleak (EL1a) include proximal balloon dilation, proximal aortic cuffs, large-caliber balloon expandable stents in the aneurysm neck, fenestrated aortic cuffs and chimney grafts; standard methods for distal type 1 endoleaks (EL1b) are distal endograft extension [3][4][5][6]. A small minority of patients are not suitable for these procedures due to adverse anatomy such as a short or highly angulated proximal neck or severe comorbidities prohibiting general anesthesia or open surgical repair. Some patients may have persistent EL1a or EL1b despite treatment with the standard methods stated above.

Transcatheter embolisation offers an alternative percutaneous approach for EL1 management in patients who are unsuitable or refractory to conventional treatments.

There is limited literature on the feasibility and effectiveness of embolisation for type 1 endoleaks. We have previously reported our initial experience in six EL1 cases following conventional EVAR in 2012 [5]and more recently with 7 cases following Nellix endovascular aneurysm sealing (EVAS) (Endologix, Santa Rosa, CA) aortic repair[7]. In this article we present our results in a larger cohort with longer follow-up data.

**Material and Methods**

***Patients***

This is a retrospective observational study at a tertiary referral center. From Oct 2010 to August 2015, 25 patients (20 men, 5 women; mean age 80 yrs; range 64-96 yrs) underwent a total of 27 EL1 embolisation procedures.

Transcatheter embolisation was selected for treatment in each patient after review and discussion in a multi-disciplinary meeting. Informed written consent was obtained in all patients prior to treatment. Embolisation of the endoleaks was selected as the treatment option for patients deemed unsuitable or refractory to conventional treatments. For patients, who had undergone EVAS with Nellix endografts, embolisation was the primary treatment in view of the very limited alternative methods for EL1 treatment after EVAS.

A total of 27 EL1 embolisation procedures were performed in 25 patients. Of the 25 patients, 23 had undergone aortic repair for abdominal aortic aneurysm, 1 for thoracic aortic aneurysm and 1 for a thoraco-abdominal aneurysmal dissection of the aorta. Twenty three patients presented with a proximal type 1 endoleak and 2 with a distal type 1 endoleak. Of the latter two, one endoleak related to the distal end of a thoracic endograft and another to the distal end of an aorto-uni-iliac (AUI) endograft. The endograft type in each patient who underwent embolisation is presented in Table 1.

Table1: Stent graft used for EVAR.

|  |  |
| --- | --- |
| Stent graft | Number of patients |
| Nellix | 11 |
| Zenith | 7 |
| Endurant | 4 |
| Captivia | 1 |
| Ventana | 1 |
| FEVAR | 1 |

***Embolisation technique:***

The embolisation technique has been previously fully described [5]. The standard technique is described briefly below.

Retrograde common femoral artery (CFA) access is obtained.

For EL1a embolization, a 45cm 6 French sheath (e.g. Destination, Terumo, Japan) is advanced into the aorta with the sheath tip a few centimeters below the top of the endograft. An aortogram is performed to assess the size, geometry and neck of the endoleak. In the majority of procedures, reverse curved shaped catheter (e.g. 5Fr Simmons (Cook Inc, Bloomington, IN, USA)) is used to selectively catheterise the endoleak cavity. A microcatheter (e.g. 2.7F Progreat (Terumo Corporation, Japan), Marathon or Echelon (Medtronic, Santa Rosa, CA) or 2.95F PX SLIM (Penumbra, Alameda, California)) is advanced co-axially into the endoleak cavity. An endoleakogram is performed to better define the size of the endoleak and evaluate for the occasional presence of any exit vessels. The endoleakogram can also be utilized as a road map for the embolisation.

Embolisation is performed with Onyx only or coils and Onyx together. If coils are used in combination with Onyx, the authors favour the use of detachable coils e.g. Ruby (Penumbra) or Concerto (Medtronic) because of the potential for coil misplacement and migration out of the endoleak cavity. Coils are deployed to form a scaffold in the endoleak cavity. Onyx is injected into the interstices between the coils to achieve complete occlusion of the endoleak cavity. Close intermittent fluoroscopic surveillance is used whilst injecting Onyx, given the risk of Onyx reflux; particularly in wide-necked endoleaks. Injection of Onyx is stopped upon complete filling of the endoleak cavity. A completion aortogram is performed to assess for residual endoleak filling (Fig 1).

For EL1b embolization, the procedure and steps are similar, apart from the use of a short regular sheath at the access site, angiography being performed at the distal end of the graft and the use of an angled-tip catheter (e.g. cobra) to engage the endoleak cavity (Fig 2).

EL1a embolisation following Nellix EVAR entails certain considerations which have been explained in details in another publication by the authors [7]. Finally, in cases where endoleak access is difficult from a CFA approach, a brachial puncture may be used.

***Definition of success and follow-up***

Technical success was defined as the elimination of the endoleak on completion angiography. Freedom from endoleak recurrence was defined as no visible residual endoleak on follow-up imaging. Freedom from sac growth was defined as a stable or decrease in aneurysm sac diameter. All patients were followed up clinically and by interval imaging according to standard local protocols. Follow-up imaging was performed by Duplex US, CTA or both.

***Imaging***

All CT angiography (CTA) scans were reviewed by a senior vascular interventional radiologist with more than 20 years’ experience. Aneurysm sac diameter before and after EVAR; and following embolisation were measured at the largest short-axis axial dimension. A change of more than 5mm was deemed significant. Duplex US scans were performed by specialised vascular sonographers.

CTA scans are performed using the GE VCT 64 slice scanner (GE Healthcare, Waukesha, WI, USA) following administration of 90mls non-ionic contrast medium 300mgI/ml at 5mls/s via a power injector into an 18G venous access catheter in the antecubital vein. Scans are extended from the thoracic inlet to the common femoral artery (CFA) bifurcation and scan delay is determined by bolus tracking over a region of interest over the aorta.

**Results**

Of the 27 cases that were embolised, the diagnosis of endoleak was based on CTA in 23 and on Duplex US in 4 cases. The average aneurysm sac size prior to embolisation was 8.2 cm (range 5.3-12.9cm). The average time between EVAR and endoleak diagnosis was 685 days (range 1-4220). In 7 patients the endoleak was diagnosed within 10 days following EVAR, in 2 between 11 days and 7 months and in 16 patients after 7 months. The average time from Endoleak diagnosis to embolisation was 27 days (range 2-94).

In 25 procedures, access was via the CFA, and in two procedures, brachial artery access was employed. Detachable microcoils (2-11of Ruby (Penumbra Inc, CA) or Concerto (EV3 Inc, USA) ranging between 4 to 12 mm), and Onyx (2-83mls) depending on the size of the endoleak were used for embolisation. Onyx alone was used in 16 procedures, and Onyx in combination with coils was used in 11 procedures.

***Procedural outcome***

Immediate technical success with complete occlusion of the endoleak on post-embolisation completion angiography was achieved in all cases (100%).

There were six procedural complications, none of which had long-term sequelae. Three patients developed puncture site hematomas, two of which required surgical revision. There were three cases of Onyx reflux at the end of the embolisation procedure. Two of these happened within one of two Nellix endograft limbs and were both treated successfully by placement of an additional stent to affix the onyx between the outside wall of the newly placed stent and the inside wall of the Nellix endograft. In another patient with a conventional AUI endograft, a small amount of Onyx reflux into the right iliac endograft was observed. However, this was not thought to be significant at the time and was not treated. This reflux did not cause symptoms and was not apparent on follow-up CT imaging.

***Follow-up***

The mean imaging follow-up available post-embolisation is 311 days (range 1-1357). Of the 25 patients, 10 patients had both CTA and US follow-up, 12 US only and 2 CTA only. 1 patient had no follow up imaging and has been excluded from the follow-up analysis.

During the follow-up period, 7 patients developed recurrent EL1 (table 2). Two patients underwent a second embolisation procedure. Of these two patients, one patient has had no further endoleak recurrence. The other patient (patient 2) had initially presented with CT evidence of contained/impending sac rupture and significantly enlarged aneurysm sac size (from 5 to 9.9 cm) due to distal migration of the endograft causing a large 1a. Both embolisation procedures were performed on the basis that they would likely be ‘palliative’ rather than curative measures. He survived 5 months following the second embolisation procedure before succumbing to sac rupture. Of the other 5 cases of endoleak recurrence, two were successfully managed by aortic cuff placement and Nellix endograft placement, one had a persistent endoleak despite subsequent aortic cuff placement and died from sac rupture nearly two and a half years following the embolisation. The other two were deemed unsuitable for further intervention due to multiple co-morbidities and endoleak morphology. One of the latter two patients has also dies from sac rupture. 1 patient died from non-vascular causes. The freedom from endoleak recurrence at a mean follow-up of xxxxx was y%.

Table 2. Patients with endoleak recurrence.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Patient | Endograft | Endoleak | Pre-embolisation Sac size (mm) | Embolisation agent | Post-embolisation sac size (mm) | Time from embolisation to recurrent endoleak diagnosis | Outcome |
| 1 | Zenith | 1a | 72 | Onyx | 75 | 50 | Failed proximal balloon dilation prior to embolisationSubsequently successfully treated with placement of an aortic cuff  |
| 2a\* | Zenith | 1a | 99 | Onyx | 129 | 4 | Small endoleak visible on followup imaging Underwent second embolisation procedure. |
| 2b | Zenith | 1a | 129 | Onyx | 160 | 57 | Second embolisation procedure, as palliative measureUnsuitable for further treatment due to wide endoleak neck.Deceased 146 days post-embolisation due to sac rupture. |
| 3a | Nellix | 1a | 62 | Onyx+coils | 56 | 360 | Endoleak successfully treated following second embolisation. |
| 4 | Endurant | 1a | 90 | Onyx | 130 | 350 | Unsuitable for further treatment due to multiple comorbidities including renal failure and dilated cardiomyopathyDeceased 452 days post-embolisation due to sac rupture. |
| 5 | Zenith | 1a | 74 | Onyx | 83 | 530 | Endoleak persisted despite subsequent aortic cuff placement.Deceased 882 days post-embolisation from non-vascular cause |
| 6 | Endurant | 1a | 101 | Onyx | 104 | 268 | Successfully treated by realigning of aorto-iliac endograft with Nellix stents |
| 7\* | Endurant | 1a | 70 | Onyx | 80 | 108 | Unsuitable for further intervention due to endoleak morphology and multiple comorbidities including cancer and cirrhosis.Deceased 121 days post-embolisation due to sac rupture. |

\*Patients 2 and 7 had presented with EL1a approximately 1 year and 3 years post EVAR with distal migration of the proximal endograft, large 1a endoleaks and evidence of contained/impending sac rupture.

In terms of sac size, of 26 cases of EL1 embolisation with follow-up imaging, 10 showed a decrease in sac size (38.5%), 10 stable sac size (38.5%)and in 6 there was an increase in the sac size (23%). The 8 cases of endoleak recurrence (two in the same patient) were observed in 5 cases with an increase in sac size, 2 with a stable sac size and 1 with reduced sac size (table 3). There was a trend for higher rates of endoleak recurrence and increasing sac size post-embolisation in cases with a large aortic sac size at embolisation (table 4 and 5).

Table 3. Sac size on imaging follow-up (available for 26/27 embolised endoleaks)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Number of cases | % | Recurrent endoleak |
| Decrease >0.5cm | 10 | 38% | 1/10 (10%) |
| Stable | 10 | 38% | 2/10 (20%) |
| Increase>0.5cm | 6 | 24% | 5/6 (83%) |
| Total | 26 | 100% | 8/26 (31%) |

Table 4. Relationship between endoleak recurrence and sac size.

|  |  |  |
| --- | --- | --- |
|  | Cases with endoleak recurrence | No endoleak recurrence |
| Pre-embolisation sac size | No. of cases | % | Deceased | No. of cases | % | Deceased |
|  <69 | 1 | 13% | 0 | 9 | 47% | 0 |
| 70-89 | 3 | 27% | 1 | 6 | 32 | 0 |
| ≥90 | 4 | 50% | 2 | 4 | 21% | 0 |
| Total | 8 |  | 3 | 19 |  | 0 |

Table 5. Relationship between change in sac size post embolisation and size of aortic sac pre-embolisation.

|  |  |  |
| --- | --- | --- |
|  | Increased sac size | Stable/reduced sac size |
| Pre-embolisation sac size | No. of cases | % | Deceased | No. of cases | % | Deceased |
|  <69 | 0 | 0 | 0 | 7 | 35% | 0 |
| 70-89 | 2 | 33% | 1 | 9 | 45% | 0 |
| ≥90 | 4 | 67% | 2 | 4 | 20% | 0 |
| Total | 6 |  | 3 | 20 |  | 0 |

The freedom from sac growth after embolisation at a mean follow-up of xxxxx was y%.

Seven of the 8 endoleak recurrences had been embolised with Onyx only and in only 1 patient had a combination of Onyx and coil been used (table 4).

Table 6. Embolisation agent used in cases with and without endoleak recurrence.

|  |  |
| --- | --- |
|  | Embolisation agent used |
|  | Onyx | Onyx and coils |
| No endoleak recurrence | 9 | 10 |
| Endoleak recurrence | 7 | 1 |
| % of endoleak recurrence | 44% | 10% |

**Discussion**

There is general consensus on the need for early treatment of Type 1endoleaks [8]. Where conventional techniques have failed or are unsuitable and there is prohibitive surgical risk, transcatheter embolisation offers an alternative management option[9]. The procedure is not generally long, does not require general anesthesia, and can be performed as a day case.

Transcatheter EL1 embolisation was first described in 1997 by Golzarian et al[10], who reported on embolisation of 8 peri-graft endoleaks including 5 EL1 cases (3 with EL1a and 2 EL1b) using coils only or coils and gelatin sponge with technical success in all cases (4-9 months follow-up), one patient requiring a repeat procedure. The same authors later briefly described their updated results as part of a review article on endoleak management, with reported technical success in 29 of 32 cases and of 24 patients followed up, two showing recurrent endoleaks[11]. There have since been several published case series using a variety of agents including coils, gelfoam, glue, thrombin and NBCA (N-butyl cyanoacrylate (NBCA), or a combination of these. Additionally there have been several case reports on EL1 embolisation[12][13][14–17]. The available published evidence of EL1 embolisation is illustrated in table 5 –. Amesur et al (1999)[18] described coil embolisation of 4 EL1b and 1 EL1a ; two of whom (one 1a and one 1b) required repeat embolisation; with complete endoleak exclusion and decrease in sac size achieved in all cases. Maldonaldo (2003)[19] successfully embolised 12 of 13 EL1a and 3 of 4 EL1b using the liquid adhesive n-butyl 2-cya- noacrylate (n-BCA) with or without thrombin. Choi et al (2011)[20] reported successful EL1 embolisation in 6 of 7 patients (5 with type EL1a, 1 with EL1b, and 1 with type Ia and Ib endoleaks); 3 required two embolisation sessions. N-butyl cyanoacrylate (NBCA) with or without coils was used via either a percutaneous transabdominal (n=5) or a transcatheter (n=5) approach.

More recently Onyx has been used for embolisation. Henrikson and colleagues reported 100% technical and clinical success in 5 EL1a and 1 EL1b endoleaks with a follow-up of 3-18 months. Eberhardt et al (2014) successfully embolised 6 patients with EL1a and 2 with EL1b with once case of EL1a recurrence.

We have previously reported our early experience on EL1 embolisation with Onyx in 6 patients after conventional EVAR[5] and in 7 patients after Nellix EVAS. This article reports the early and mid-term outcomes in 25 patients who have undergone a total of 27 embolisation procedures. Whilst technical success based on elimination of endoleak on completion angiography post-embolisation was achieved in all 27 procedures, there were a total of 8 endoleak recurrences, two in one patient who had two embolisation procedures. This is the largest reported series of patients with EL1 who have undergone embolisation using Onyx (or Onyx and coils) to date.

EL1a embolisation is usually a procedure of last resort, when other bail-out techniques have failed or are not possible. The one exception is when Nellix endografts are used for EVAR. These consist of two balloon-expandable stents running from the iliac artery to the non-aneurysmal aorta and provide sealing of the aneurysm through polymer filled endobags which surround the stent. Patients with Nellix endografts are not suitable for conventional EL1a treatments and at our center transcatheter embolisation is the primary way of managing proximal endoleaks with these endografts. Moreover, our results show a more favourable embolisation outcome with Nellix endografts compared with conventional endografts with only one case of endoleak recurrence in 11 patients in this series; and this was subsequently successfully managed with a second embolisation procedure.

The other notable trend in our cohort is that of better outcomes when Coils and Onyx are used together compared to when Onyx is solely used. When the former technique is used, we initially deploy detachable coils in the endoleak cavity with coils to form a ‘scaffold’ for subsequent complete occlusion of the endoleak by Onyx embolization. In our experience this approach has also minimized the risk of non-target embolization; and of the three cases of Onyx reflux in our cohort, two were embolised without the use of coils.

Regarding whether there any specific morphological characteristics of type 1 endoleaks that are favourable predictors for a successful and durable embolisation outcome, we have noticed that large endoleak cavities and endoleaks with a wide-necked communication (endoleak entrance) with the native artery lumen are more difficult to embolise and seem to have a less durable outcome.

Large endoleak cavities require a large volume of embolic agent and it is difficult to occlude the cavity completely in these cases. If the endoleak cavity is large, successful endoleak occlusion may be achieved by occluding the entrance into the endoleak. Wide necked endoleaks pose a particular challenge, as these exhibit an inherent high risk of Onyx reflux which is further elevated by the need to achieve a complete seal of the endoleak cavity, which requires embolic agent to be placed at the endoleak neck. If we have to embolise an endoleak with a wide neck, a combination of detachable coils and Onyx seems to be optimal.

We have not performed an analysis of morphological endoleak characteristics to determine an unfavourable threshold value for endoleak cavity size or endoleak entrance diameter for embolisation. However, we believe that an endoleak cavity volume of more than 30ml and an endoleak entrance of more than 15mm are unfavourable predictors of early or late success.

As a result of our experience, we do not advocate embolisation for all patients with EL1 that are unsuitable for standard therapies. However, there are few situations where embolisation cannot be attempted, and whilst in cases such as those with large endoleak cavities or wide endoleak entrances embolisation is unlikely to provide a long term sustained endoleak occlusion; these patients may benefit from EL1 embolisation as a ‘palliative measure’ to prevent sac growth and rupture for as long as possible (Fig 3 and 4). In this series, palliative endoleak embolisation prolonged the life of the two patients who presented with a contained abdominal aortic aneurysm rupture for 5 and 4 months, proving that palliative embolisation should be considered in patients without any other alternative.

Imaging follow-up post Onyx embolisation is somewhat complicated by significant streak artifact from tamsulosin content of Onyx; which can make identification of a persistent or recurrent endoleak difficult. Duplex US is not limited by Onyx and can thus offer improved sensitivity for detection of a recurrent endoleak. Contrast enhanced US can offer additional sensitivity in equivocal cases.

In summary, this series is the largest cohort of patients with type 1 endoleaks who have undergone embolisation with Onyx or Onyx and coils. Transcatheter embolisation of type 1 endoleaks provides a safe and sustainable treatment option for patients refractory or unsuitable for conventional EL1 therapeutic options. Embolisation has a high technical success rate, a low endoleak recurrence rate and the majority of patients are free from aneurysm sac growth. Patients with large endoleak cavities and wide endoleak entrances may have less predictable outcomes after embolisation, although freedom from aortic rupture and freedom from sac growth may be a desirable therapeutic goal of embolisation in these patients.

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