Repairing immediate proximal endoleaks during abdominal aortic aneurysm repair

Ravi R. Rajani, MD, Zachary M. Arthurs, MD, Sunita D. Srivastava, MD, Sean P. Lyden, MD, Daniel G. Clair, MD, and **Matthew J. Eagleton, MD,** *Cleveland, Ohio*

Introduction: **Successful endovascular exclusion of abdominal aortic aneurysms is largely dependent on adequate apposition of the stent graft to the aortic wall. Proximal endoleaks at the time of stent graft placement are uncommon but are more prevalent in patients with challenging neck anatomy. If these initial leaks do not respond to simple balloon angioplasty, Palmaz stents (Cordis Endovascular, Warren, NJ) and covered stent graft cuffs both have been used to seal the endoleak. Long-term data regarding the efficacy of one method over the other, however, is lacking.**

Methods: **We retrospectively reviewed a database of all infrarenal aortic aneurysm repairs with an intraoperatively diagnosed type Ia endoleak requiring Palmaz stent or covered stent graft cuff placement. Fenestrated and branch grafts were excluded. All records and appropriate imaging studies were reviewed. The primary end points were technical success of aneurysm exclusion, recurrence of a type Ia leak, and need for reintervention.**

Results: **At the time of the initial aneurysm repair, 72 patients required an adjunctive covered extension or Palmaz stent; of these, 24 (33%) underwent sole placement of a Palmaz stent, 45 (62.5%) underwent placement of a covered stent graft cuff, and 3 required both a cuff and a Palmaz stent. Aneurysmal exclusion was successful in all patients before leaving the operating room. No recurrent type Ia endoleak developed in patients who underwent Palmaz stent placement. Of the 45 patients who underwent cuff placement, proximal leaks developed in 3 that required reintervention: 1 was managed with a Palmaz stent and the other 2 required open surgical revision.**

Conclusions: **Palmaz stent placement and stent graft cuff placement are frequently used to seal immediate proximal endoleaks that do not resolve with balloon angioplasty. Both methods appear to be durable long-term options to facilitate endovascular exclusion of abdominal aortic aneurysms. (J Vasc Surg 2011;53:1174-7.)**

Endovascular repair of abdominal aortic aneurysms (EVAR) has undergone progressive evolution since it was first described in 1991.[1] Continued experience with the procedure and refinements in device technology have led to improvements in short-term and long-term outcomes. Adequate proximal neck seal is the primary step toward complete aneurysm exclusion, and disadvantaged neck anatomy remains the most common contraindication to EVAR.[2] All commercially developed stent graft designs have a set of strict neck criteria for proper use. As experience with EVAR has expanded, however, an increasing number of patients with nonideal neck anatomy are being treated, with promising results.[3] A number of adjunctive techniques have subsequently been developed to aid with proximal fixation at the time of the initial aneurysm repair.

Immediately after stent graft placement, the simplest option to adequately seal the proximal neck is through the use of a gentle molding angioplasty balloon, as recommended by the manufacturers of all commercially available devices. Angioplasty is often successful, particularly if the stent graft has been appropriately sized, positioned, and deployed. When molding angioplasty is not able to achieve adequate seal, a further intervention may be necessary. If the stent graft has been undersized or maldeployed, there may be sufficient proximal neck length to place a proximal extension graft.[4] Care must be taken, of course, to preserve the renal artery ostia while still achieving proximal seal. When there is not sufficient length to place an extension, a large balloon-expandable stent, such as the Palmaz (Cordis Endovascular, Warren, NJ), can be placed to promote apposition of the graft to the aorta.

The use of Palmaz stent placement for intraoperative proximal endoleaks has been reported.[5-7] Although these series have consisted of small numbers of patients, they have all reported a high primary assisted technical success rate and a high rate of short-term endoleak exclusion. It remains unclear if Palmaz stent placement carries with it any long-term complications, including the potential development of type I endoleak from neck enlargement or type III endoleak from a fabric tear.

Extension cuff or Palmaz stent placement are the most commonly performed endovascular options to achieve initial proximal seal, but open surgical options are available. The placement of periaortic sutures has been described but appears to be associated with higher perioperative mortality than endovascular techniques. If the aneurysm cannot be excluded at the time of stent graft placement, consideration should be given to conversion to open repair. Unfortunately, outcomes after emergent conversion may be associated with a perioperative mortality rate as high as 20%.[8]

From the Department of Vascular Surgery, Cleveland Clinic Lerner College of Medicine–Case Western Reserve University.

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Reprint requests: Matthew J. Eagleton, MD, Department of Vascular Surgery, H32, Cleveland Clinic Foundation, 9500 Euclid Ave, Cleveland, OH 44195.

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Given the lack of data assessing long-term outcomes after immediate endoleak, we sought to analyze the technical success of cuff and Palmaz stent placement and the long-term failure rate of treated patients.

METHODS

After approval of the Institutional Review Board, the Cleveland Clinic Department of Vascular Surgery database was queried for all endovascular aortic aneurysm repairs that were associated with an adjunctive procedure during an 8-year period (January 2001 to July 2009). An adjunctive procedure was defined as any additional stent or stent graft needed at the time of initial aneurysm repair. We excluded patients involved in investigational trials, including placement of branched or fenestrated devices. A review of patient demographics, operative notes, and imaging studies identified 72 patients who had undergone placement of a proximal extension cuff of Palmaz stent.

All patients underwent preoperative spiral computed tomography angiography to assess aortic morphology and suitability for endovascular repair. Multiplanar reconstruction and centerline flow analysis were incorporated once available. The use of preoperative calibration angiography was left to the discretion of the treating surgeon and was used more frequently in the first several years. Described techniques were used to implant commercially available infrarenal devices in all patients in the operating room. Grafts were placed within standard instructions for use guidelines, particularly in regard to the size of the aortic neck. Completion angiography was used for endoleak detection, and all patients underwent molding balloon angioplasty of the proximal neck.

If a proximal endoleak was present after molding angioplasty, further intervention included placement of a proximal covered extension cuff or the use of a Palmaz balloon-expandable stent. The method of intervention was at the judgment of the operating surgeon, with a preference for placing a fabric-covered cuff if there was felt to be sufficient room below the renal arteries and a Palmaz stent if there was not.

Cuffs were placed according to the type of stent graft used, with all attempts made to match extension cuffs with the type of graft placed. Cuff sizing was left to the discretion of the treating physician but generally matched the diameter of the initially placed graft. Palmaz stents were positioned across the renal arteries and top of the stent graft. In several patients, a covered cuff and a Palmaz stent were placed to protect the aorta from the theoretic risk of a bare metal stent being placed in direct apposition to it. Because the cuff was placed purely for prophylactic protection at the discretion of the surgeon, these patients were grouped with those that were treated with a stent alone.

Patient records were reviewed, including all demographics, imaging studies, and follow-up information. The primary end points were technical success of aneurysm exclusion, recurrence of proximal endoleak, and need for reintervention or operative aneurysm repair. Patient follow-up was performed according to previously suggested guidelines, with most patients being monitored with contrast-enhanced computed tomography (CT) scans (initially at 3-month intervals). The follow-up analysis excluded patients who did not have a follow-up CT scan more than 3 months after their initial operation.

Table I. Summary of demographics between Palmaz stent and covered extension groups[a]

Variable	*Palmaz stent*	*Covered extension*
Patients, No.	27	45
Age, years	78	79
Men, No. (%)	19 (70)	36 (80)
Aneurysm diameter, cm	6.1	6.1
Emergent procedures, No.	3	0

[a] $P < .05$ for all categories.

RESULTS

Within the specified date range, 1209 endovascular aortic aneurysm repairs were identified, and 72 patients (5.9%) who required placement of an extension cuff or Palmaz stent were selected. Forty-eight (67%) had sufficient infrarenal aorta remaining to undergo placement of a covered extension cuff, and 24 (33%) were not felt to be candidates for proximal graft extension and instead underwent placement of a Palmaz stent. A residual proximal endoleak was present in three patients in the extension cuff group, and they also underwent Palmaz stent placement; these patients were included with the Palmaz subgroup. There were no significant demographic differences between those patients who underwent cuff or Palmaz placement (Table I). All 72 patients were able to be treated endovascularly, for a primary assisted technical success rate of 100%. No patient left the operating room with an unsealed proximal endoleak. No perioperative deaths occurred in either group. A variety of commercially available stent grafts were placed, and no specific graft was associated with an increased rate of immediate endoleak.

No recurrent endoleak developed in patients who received a Palmaz stent. A proximal endoleak developed in three patients (6%) who initially were treated with extension cuffs (Table II):

- The first presented with CT evidence of perigraft flow and a persistent aneurysm sac at 1 year. Angiography confirmed a loss of proximal fixation; fortunately, the aneurysm could be excluded by placement of a Palmaz stent.
- The second patient underwent EVAR in 2003, which was complicated by an intraoperative proximal endoleak requiring cuff extension as well as a limb occlusion requiring emergent femoral-femoral bypass. The remaining aorta slowly developed aneurysmal degeneration, which was accompanied by a recurrent proximal endoleak. He ultimately underwent successful staged hybrid repair of his group III thoracoabdominal aneurysm, which remains excluded.

Table II. Summary of patients who developed recurrent proximal endoleaks

Pt	*Initial repair method*	*Time to recurrence*	*Presentation*	*Repair method of recurrence*
A	Covered extension	3 months	Perigraft flow on surveillance CT scan	Palmaz stent placement
B	Covered extension	60 months	Development of group III TAA	Staged hybrid repair
C	Covered extension	12 months	Sac enlargement on surveillance CT scan	Failed attempted Palmaz stent; graft explanted

CT, Computed tomography; *TAA,* thoracoabdominal aneurysm.

- The final patient underwent EVAR in 2000, including placement of a proximal extension cuff. Sac enlargement was noted at the 1-year follow-up, and angiography confirmed a proximal endoleak. An attempt was made at placing a second proximal extension cuff as well as a Palmaz stent, but aneurysm exclusion was not achievable. He underwent graft explant with open repair, which he survived without complication.

Of the total 72 treated, 47 (65%) had a contrast-enhanced CT scan at least 3 months after their initial repair and were included in the outcome analysis. In the cuff group, 31 of the 45 patients (69%) were included, and 16 of the 27 patients (59%) in the Palmaz group were included. The average length of time from aneurysm repair to the last reviewed CT scan was 755 days for the cuff group and 1047 days for the Palmaz group. Other than the three patients described, no other recurrent type Ia endoleak developed.

DISCUSSION

We found that 6% of endovascular infrarenal aneurysm repairs performed were associated with an immediate proximal endoleak, similar to previously reported results. The current approach of most surgeons is to aggressively treat the endoleak and ensure complete aneurysm exclusion. Refinements in stent graft deployment technique and in construction have largely been made in an attempt to facilitate proximal seal. Transrenal stenting,[9] endostapling,[10] graft oversizing, and open aortic neck banding are several examples of the myriad different methods that have been tried to improve the proximal seal. The simplest maneuvers, however, remain covered stent graft extension or placement of a Palmaz stent. Placement of a proximal extension piece obviously depends on having sufficient infrarenal aortic neck to place the cuff without compromising the renal artery ostia. If there is inadequate neck to land a covered extension, a Palmaz stent may allow aorta-graft apposition with sac exclusion. The stent is balloon-mounted, and precise positioning may be facilitated by partially deploying it within a sheath before full inflation.[11] Placement of a Palmaz stent does carry a theoretic long-term risk of graft erosion, which was not realized in any of our patients.

Approximately two-thirds of these patients had a CT scan at least 3 months after their aneurysm repair, with the average interval being >2 years. The Palmaz and cuff groups had similar availability rates of CT for review, and the duration between repair and the last CT scan was similar. Three late failures occurred in the current series, all of which were in patients who underwent placement of a covered extension. Aneurysmal degeneration of the remaining aorta developed in one patient, which appeared to be diseased at the time of the initial aneurysm repair in 2000. At that time, endovascular and hybrid options for treating thoracoabdominal disease were limited, and a treatment course consisting of infrarenal repair, followed by serial imaging of a clearly diseased aortic segment seems reasonable. Fortunately, that patient was successfully treated without significant morbidity. The other two late failures were felt to be successfully excluded at the time of initial repair but presented with persistent sac perfusion on serial imaging. Both required diagnostic angiography to identify a proximal endoleak, and the first was treated with a Palmaz stent. The second, unfortunately, suffered from eventual dilatation of the aortic neck, which was not amenable to endovascular repair. The patient ultimately required graft explant, which he survived without noteworthy morbidity.

CONCLUSIONS

Although there was no statistically significant difference in long-term success between the covered extension group and the Palmaz group, it is important to note that all recurrent endoleaks developed in patients who had a cuff placed. It remains unclear if the true etiology of late proximal endoleak is neck degeneration or device migration. In theory, the radial force of an additional covered piece may promote neck dilatation and loss of aortic wall apposition. Furthermore, the placement of a transrenal Palmaz stent may inhibit future migration of the stent graft. Fortunately, the rate of late proximal endoleaks remains low, and the current study was underpowered to elucidate a significant difference in leak rate between the two repair methods. As the indications for endovascular aneurysm repair continue to broaden—particularly with the introduction of branch graft devices and hybrid approaches[12]—the technical aspects of covered extension and Palmaz stent placement will remain valuable for ensuring adequate seal and aneurysm exclusion.

AUTHOR CONTRIBUTIONS

Conception and design: RR, ZA, SS, SL, DC, ME
Analysis and interpretation: RR, SS, SL, DC, ME
Data collection: RR, ZA
Writing the article: RR, ME

Critical revision of the article: RR, ZA, SS, SL, DC, ME
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