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Multicenter experience in translumbar type II endoleak treatment in the hybrid room with needle trajectory planning and fusion guidance

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ABSTRACT

Objective: The objective of this study was to evaluate the efficacy of treating type II endoleaks (T2Ls) after aortic endovascular repair with image guidance translumbar puncture using intraoperative cone beam computed tomography with preprocedure computed tomography angiography fusion in hybrid operating rooms.

Methods: Twenty-six consecutive T2L patients in three different institutions were treated between March 2015 and September 2017 by direct translumbar puncture of the abdominal aortic aneurysm (AAA) sac after previous endovascular aortic repair. All patients were treated at a single setting in a cardiovascular hybrid operating room with a workstation featuring needle trajectory planning and guidance software. Aneurysm sac size change from the index treatment, freedom from recurrent endoleak after treatment, demographics, risk factors, and procedure factors were analyzed with univariate analysis.

Results: All patients (N = 26; 19 male, 7 female; age range, 59-95 years; mean body mass index, 27.44 ± 3.06 kg/m^2) underwent treatment for AAA sac expansion or symptoms. Four patients had failed to respond to previous catheter-directed T2L treatment. The most common risk factors included hypertension, hypercholesterolemia, coronary artery disease, tobacco use, and diabetes. Time to initial endoleak diagnosis ranged from 2 to 1914 days (average, 404 days). Aneurysm size after initial repair was 60.3 ± 7.5 mm; sac size had increased 10.1 ± 6.5 mm at the time of treatment. Onyx (Medtronic, Irvine, Calif) or glue (*n*-butyl cyanoacrylate) and coil embolization was used in 20 cases, and 6 patients were treated with coiling alone. There was no difference between the patients treated with coils alone and those treated with coils or glue ($P > .05$) in terms of freedom from failure. Total procedure time was 75.9 ± 40.7 minutes; contrast material volume, 19.9 ± 29 mL; fluoroscopy time, 13.74 ± 12.2 minutes; and radiation dose, 121.16 ± 167.7 mGy. After embolization, the mean sac diameter decreased by 2.2 mm to 67.5 ± 9.8 mm. Average follow-up period was 214 days. In 19 patients, the sac reduced in size between 0.2 and 19.1 mm per 100 days; in 2 patients, there was continued AAA expansion (3.4-4.3 mm per 100 days); there was no change in the sac size in 5 patients after the procedure. There were no AAA ruptures during the study period. Once T2L was treated, the recurrence rate was low at 11.5%.

Conclusions: This initial multicenter evaluation of the effectiveness of fusion image-guided translumbar obliteration of T2L demonstrated that the technique was effective at all three study centers and showed excellent efficacy to reduce AAA sac size. This may become a more effective and efficient method of treating T2L compared with transarterial or transcaval embolization because of its high success rate and technical ease. (J Vasc Surg 2020;72:1043-9.)

Keywords: Type II endoleak; Translumbar embolization; CT fusion; Hybrid OR

Endovascular aneurysm repair (EVAR) is an accepted treatment for select patients with anatomically suitable abdominal aortic aneurysms (AAAs) because of its low perioperative morbidity and mortality.[1,2] Despite its success, the major shortcoming of the technique remains the need for secondary interventions for endoleaks.[3] Type II endoleaks (T2Ls) are particularly common and can often cause AAA expansion if left untreated.[4-7] The overall rate of incidence of T2L at 1 month and 6 months is reportedly ∼14% (9.8%-25%) and ∼16.3% (8.3%-16.8%),

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respectively.[8] Although investigators have reported high rates of spontaneous closure of and freedom from AAA sac enlargement when T2Ls are present, Schlösser et al[9] described T2L as one of the causes of AAA rupture after EVAR. Other investigators have reported high rates of spontaneous closure of these endoleaks and freedom from AAA sac enlargement as well.[10]

The management of T2L remains controversial because its natural course is not completely understood.[5] Most studies support conservative care with close observation. However, most investigators share the opinion that patients with AAA sac growth of >5 mm, persistent endoleak (>6 months), or significant pressure symptoms should be considered for repair.[4,6,7] Strategies for treating T2L include open surgery, transarterial, translumbar, transcaval, and laparoscopic approaches.

Some authors have advocated that the translumbar approach is less challenging and possibly more effective than the transcatheter approach because of the technical demands of embolizing the T2L through connected collaterals.[11] The translumbar technique allows direct puncture of the actual leak, thereby simplifying the technical demands of delivering the agents to obliterate the endoleak. A review of 32 retrospective studies comprising 1515 T2Ls and 393 interventions demonstrated that of the 57 translumbar embolizations, the success rate was 81% with no complications. In the same study, 120 transarterial approaches had a success rate of 62.5% and 9.2% complication rate.[11] The translumbar approach, however, is generally more difficult to perform because the patient needs to be imaged with conventional computed tomography (CT) in conjunction with angiography. The technique requires multiple CT imaging sessions and redirection of the needle apparatus to localize and to target the endoleak.

Each of the three centers involved in this report recently adopted a new, simpler method of treating T2L using CT fusion technology that allows preprocedure CT angiography (CTA) to be used in conjunction with live hybrid room noncontrast-enhanced cone beam CT (CBCT) to localize the T2L and to display needle trajectory to target for translumbar embolization. The collective initial consecutive experience is presented in this report. The technique is generally quicker, and because all the steps can be performed in one procedure or operating room, the process of treating a T2L can be safer and more tolerable for the patient. This new workflow and technique may allow effective treatment with potentially fewer patient transfers and needle insertions as well as the use of less contrast material and radiation compared with treatment with a standard translumbar approach.

We report our initial multicenter experience with this novel approach and the factors that contribute to its technical success and freedom from further endoleaks over time.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected, multicenter cohort data
- **Key Findings:** For 26 patients at three centers, there was 100% technical success of translumbar embolization for treatment of type II endoleaks. Nineteen patients had sac size reduction, whereas two showed expansion and five demonstrated no change. There were no aneurysm ruptures during the study period.
- **Take Home Message:** Computed tomography fusion-guided translumbar embolization of type II endoleaks in a modern hybrid room is a safe and reproducible technique with excellent efficacy in reducing abdominal aortic aneurysm sac size.

METHODS

Twenty-six consecutive T2L patients in three different institutions were treated between March 2015 and September 2017 by direct translumbar puncture of the AAA sac after previous endovascular aortic repair. All patients with an indication for treatment of T2L underwent the described procedure during the study period. These patients underwent angiography to rule out other types of endoleaks before being scheduled for the T2L procedure. The study was approved by each hospital's Institutional Review Board. Consent was obtained from patients before data collection and analyses.

Technique description. All cases were performed using an interventional cardiovascular hybrid operating room system (Discovery IGS; GE Healthcare, Waukesa, Wisc) and a workstation (Advantage Workstation; GE Healthcare) loaded with needle trajectory and guidance software (Needle ASSIST; GE Healthcare). Eighteen of the 26 patients were treated under general anesthesia.

The patient is positioned prone, and a noncontrast-enhanced 5-second rotational acquisition centered on the anatomy of interest is performed (CBCT; Fig 1). The images are automatically transferred to the workstation, and 0.45-mm × 24.4-cm axial slices are reconstructed. The preprocedure CTA image demonstrating the T2L is then loaded into the workstation and registered to the CBCT image using anatomic landmarks and the aortic endograft position within the sac (Integrated Registration; GE Healthcare). The CBCT image was used only to confirm the position of the needle when the target endoleak was approached. Registered volume is used to define a needle trajectory from skin line to the target entry into the aneurysm sac, avoiding any vital structures (Figs 2 and 3). The gantry is positioned in imaging position and a three-dimensional rendering of the CBCT image with the virtual needle trajectory overlaid in real time over fluoroscopy (TrackVision; GE Healthcare). An

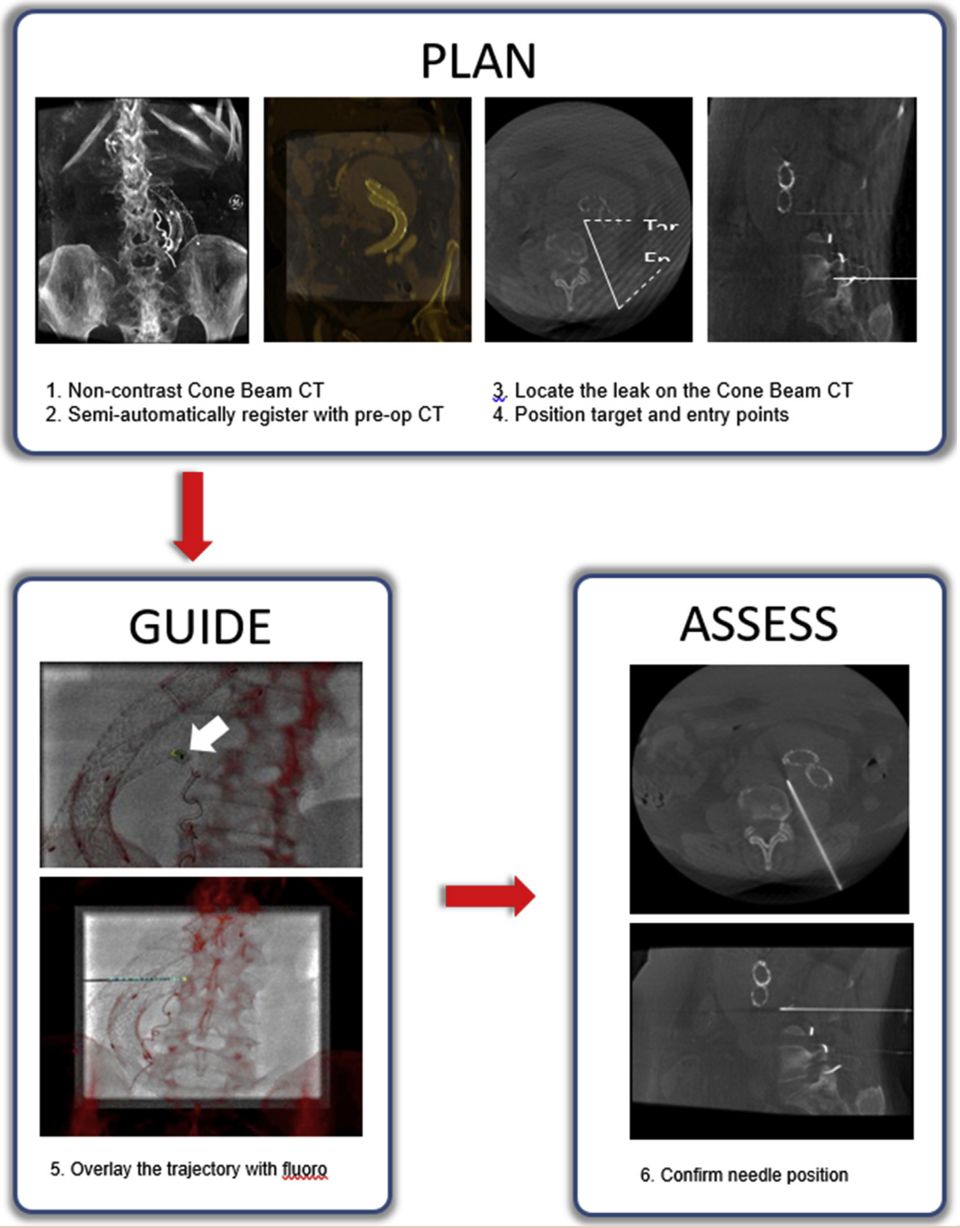

Fig 1. Work flow for fusion-guided therapy. *CT,* Computed tomography.

18-gauge Chiba needle is advanced following the trajectory pathway to the endoleak (Fig 4). The X-ray gantry is automatically positioned in a bull's-eye view to facilitate needle insertion and then to a view parallel to the needle path to follow the needle's progression. Needle position in the sac is confirmed by spontaneous blood backflow and angiography. Another 5-second noncontrast-enhanced CBCT scan is performed to verify the exact final needle position in the targeted endoleak; embolization is then performed, and the obliteration of the endoleak is confirmed. All patients were treated using coils first. The choice of using either Onyx (Medtronic, Irvine, Calif) or glue to supplement the coils was determined by the operator's preference. In general, the larger cavities also required Onyx or glue (*n*-butyl cyanoacrylate) after initial coiling. Technical success was defined as successful entry into the target endoleak region and placement of embolization agents into the defined endoleak region.

Data collection. Follow-up evaluations were conducted at 1 month, 6 months, and yearly thereafter if the T2L repair was successful. Aneurysm sac size change from the index treatment, freedom from recurrent endoleak

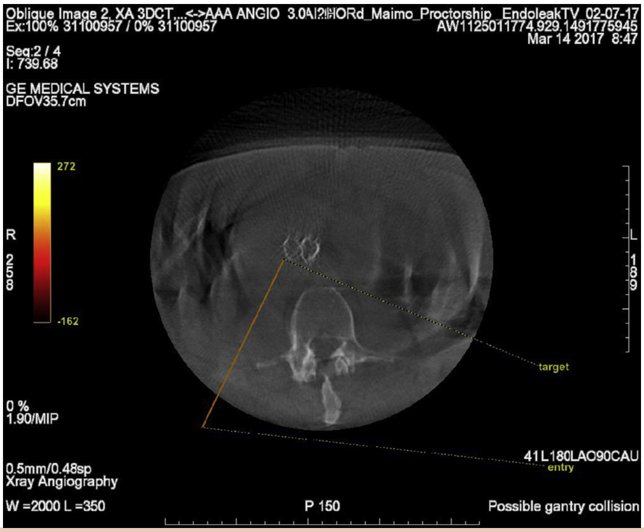

Fig 2. Planning of needle trajectory from entry point to target.

after treatment, demographics, risk factors, and procedure factors were among the data collected. AAA sac growth was defined as >5-mm expansion from the previous study. The senior investigator within the site using CT scan imaging made all measurements of AAA maximum sac size. Ultrasound data were not included in the data.

Statistical analysis. Data are presented as mean ± standard deviation for continuous variables and proportions for categorical variables. Univariate analyses were by Student *t*-tests for continuous variables and by Fisher exact test for categorical variables. Freedom from postintervention T2L was analyzed by Kaplan-Meier statistics. For all statistical analysis, data were analyzed using the SAS software (SAS Institute, Cary, NC) by an independent statistician. All tests used a level of significance <.05.

RESULTS

A total of 26 patients with ages ranging from 59 to 95 years underwent T2L treatment because of continued AAA sac expansion or symptoms after successful endovascular repair of AAAs. Two patients experienced symptoms of abdominal pain. Nine patients had been treated with fenestrated-branched EVAR and 17 with standard EVAR. Four patients had failed to respond to previous catheter-directed T2L treatment. All of these patient who failed to respond to previous catheter-directed therapy had multiple inflow and outflow vessels. The lumbar arteries were involved in the endoleak in 23 of the 26 cases. In eight cases, the inferior mesenteric artery contributed to the T2L, and two patients had renal or accessory renal artery involvement. Patient demographics and risk factors are provided in the Table.

Time to initial endoleak diagnosis ranged from 2 to 1914 days (average, 404 days) after EVAR. Mean aneurysm size at the time of T2L diagnosis was 60.3 ± 7.5 mm. The mean AAA sac size increase was 10.1 ± 6.5 mm from the baseline AAA size. The total procedure time averaged to 75.9 ± 40.7 minutes; average fluoroscopy time was 13.74 ± 12.2 minutes. The average amount of contrast material used during the procedure (including the CBCT scans during the procedure) was 19.9 ± 29 mL, and radiation dose was 121.16 ± 167.7 mGy. Onyx or glue (*n*-butyl cyanoacrylate) and coil embolization was used in 20 cases, and 6 were treated with coiling alone. The length of hospital stay was 1.92 ± 1.07 days on average.

Average follow-up period was 214 days (range, 178-320 days). After embolization, the mean sac diameter decreased by 2.2 mm to 67.5 ± 9.8 mm. In 19 patients, the AAA sac reduced in size between 0.2 and 19.1 mm per 100 days. In two patients, there was continued AAA expansion (3.4 to 4.3 mm per 100 days), whereas in five patients, there was no change in the sac size after the procedure. It is presumed that the mechanism of growth in patients without a defined endoleak was most likely due to an ongoing type IV or type V endoleak and treatment of these two patients conservatively with surveillance imaging. There were no AAA ruptures during the study period. Three of 26 (11.5%) had persistent T2L on follow-up CT. One of those patients underwent repeated translumbar embolization. Fig 5 depicts the freedom from failure of T2L after the intervention. There was no difference between the patients treated with coils alone and those treated with coils plus glue ($P > .05$). The patients with sac growth tended to be associated with higher body mass index and baseline estimated glomerular filtration rate ($P = .09$).

DISCUSSION

Despite a variety of strategies for treatment of T2L based on treatment of inflow vessels, aneurysm sac, and outflow vessels, the effectiveness has been marginal at best, with recent large series revealing a success rate of only 31.5%.[5,12] Translumbar embolization using needle trajectory and guidance in a hybrid operating room has been an available technology linked to most modern hybrid operating rooms. Similar image-guided approaches have been reported with other imaging systems[12,13]; however, this is the first report using multimodality image fusion in a hybrid operating room to reproducibly treat patients at multiple centers with significant AAA sac follow-up results. Our initial experience treating T2Ls at three different institutions using this technique revealed that combining standard CTA and CBCT imaging with real-time fluoroscopy using

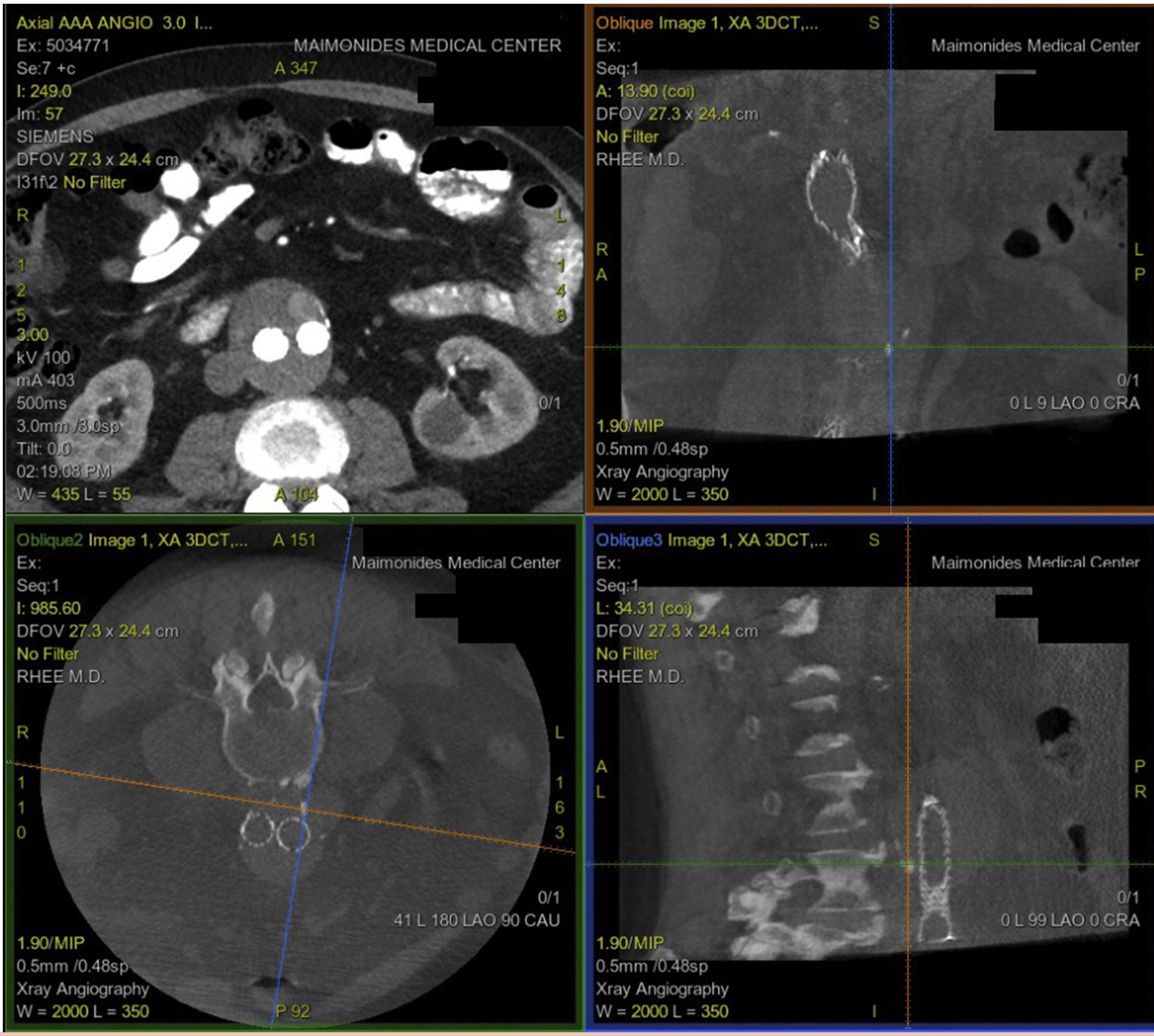

Fig 3. Coronal, axial, and sagittal views of cone beam computed tomography (CBCT) from the workstation during the planning stage.

TrackVision can accurately predict the trajectory path of the needle. Embolic agents were used in these cases in conjunction with coils to fill the entire endoleak cavity and the associated complex network of outflow tracts, which has been previously demonstrated to be more effective.[7] Our strategy is a simplified and nearly error-free method of translumbar embolization that can be performed in a setting familiar to most vascular surgeons. This approach eliminates the need for transfer of the patient from the procedure room to the angiographic suite to complete the procedure. It also allows three-dimensional trajectory to autoregister in real time, adjustment with C-arm gantry and table movements, and field of view and source-to-image distance changes in real time. This ultimately reduces not only the previously needed multiple injections of iodinated contrast agents to determine the appropriate location by standard CT-guided techniques but also the radiation exposure to patients and operators. Standard CBCT is 0.28 to 0.29 $mSv \cdot Gy^{-1} \cdot cm^{-2}$, whereas conventional CT is on average 15 $mSv \cdot Gy^{-1} \cdot cm^{-2}$ per published reports.[14]

This innovative approach is unique for the following reasons. These procedures were performed by surgeons in a hybrid operating room setup rather than in an interventional radiology suite. It demonstrated clearly that these procedures could be performed effectively and safely in the hybrid operating room. In addition, the ability to use the imaged contrasted (red color) radiographic rendering on the overlay (which simulates an X-ray projection of the three-dimensional model on fluoroscopy) allowed assessment of patient/anatomy motion and eventually adjustment of the registration. Finally, the operator had access to direct commands at tableside to automatically position the system in bull's-eye or

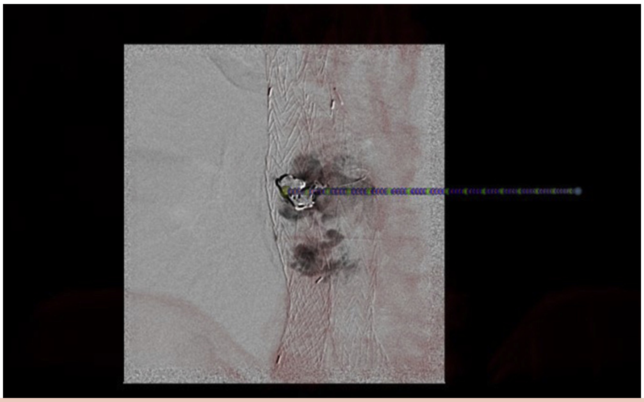

Fig 4. Aneurysm sacogram after initial placement of coils.

Table. Patient demographics and risk factors

Characteristic/comorbidity	Cases (N = 26)
Age, years	75.27 ± 8.5
Male	19 (73.08)
Female	7 (26.92)
Body mass index, kg/m^2	27.44 ± 3.06
Baseline estimated glomerular filtration rate	67.93 ± 19.30
Tobacco use	9 (34.62)
Hypertension	22 (84.62)
Hypercholesterolemia	17 (65.38)
Diabetes	7 (26.92)
Coronary artery disease	13 (50)
Congestive heart failure	4 (15.38)
Peripheral artery disease	3 (11.54)
Chronic obstructive pulmonary disease	3 (11.54)
Dialysis	1 (3.85)

Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

progress views, using both gantry and table motorized motions. This allowed precise, real-time adjustments to the needle trajectory. The midterm results demonstrated the effectiveness of this approach and were consistent with the results of other studies of translumbar treatment of T2L.

There are several limitations of this study. There is likely to have been selection bias in choosing which patients received this treatment modality. There is a lack of randomization and control group. The technique and results from this series, although promising, were compared only with historical data. The procedure itself had some variability, with the decision to use additional Onyx or glue left to the discretion of the physician. Last,

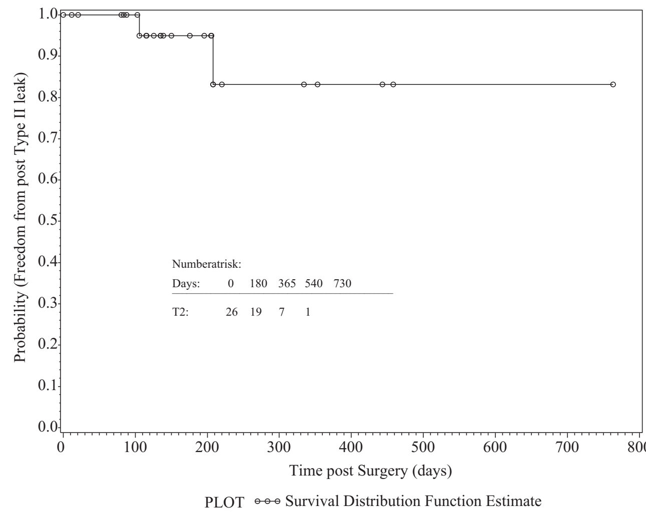

Fig 5. Freedom from postintervention type II endoleak (T2L).

the technique is dependent on having access to specific equipment and software, so it may not be feasible for everyone to replicate.

CONCLUSIONS

Our initial multicenter experience of 26 patients with T2Ls using a novel trajectory planning and guidance software program in a hybrid operating room demonstrated that the approach is feasible and readily reproducible. Translumbar T2L embolization using needle trajectory planning and fusion guidance was successful in 100% of the cases. It effectively treats complex T2Ls with limited X-ray dose and contrast media use. It allows vascular surgeons to treat complex T2Ls within the hybrid operating room arena with high technical and clinical success. This technique is generally faster than transarterial catheter-directed coil embolization, and because all the steps can be performed in one procedure or operating room without repetitive CT and patient manipulations, the T2L treatment process is more tolerable for the patient. This new workflow and technique allow effective treatment without multiple patient transfers or repeated needle insertions and with less contrast material and radiation compared with T2L treatment by the standard translumbar approach.

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AUTHOR CONTRIBUTIONS

Conception and design: RR, GO, AH, ET, MS, SH, TJ, SH

Analysis and interpretation: RR, GO, AH, ET, MS, SH, TJ, SH

Data collection: RR, GO, AH, ET, MS, SH, TJ, SH
Writing the article: RR, GO, AH, ET, MS, SH, TJ, SH
Critical revision of the article: RR, GO, AH, ET, MS, SH, TJ, SH
Final approval of the article: RR, GO, AH, ET, MS, SH, TJ, SH
Statistical analysis: RR, MS, TJ
Obtained funding: Not applicable
Overall responsibility: RR

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