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### ► **To cite this version:**

Ludovic Canaud, Thomas Gandet, Julien Sfeir, Baris Ata Ozdemir, Laurence Solovei, et al.. Risk factors for distal stent graft-induced new entry tear after endovascular repair of thoracic aortic dissection. *Journal of Vascular Surgery*, 2019, 10.1016/j.jvs.2018.07.086 . hal-01973380

**HAL Id: hal-01973380**

**<https://hal.science/hal-01973380>**

Submitted on 18 May 2020

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# Risk factors for distal stent graft-induced new entry tear after endovascular repair of thoracic aortic dissection

Ludovic Canaud, MD, PhD,<sup>a</sup> Thomas Gandet, MD,<sup>a</sup> Julien Sfeir, MD,<sup>a</sup> Baris Ata Ozdemir, MD,<sup>a</sup> Laurence Solovei, MD,<sup>a</sup> and Pierre Alric, MD, PhD,<sup>a,b</sup> Montpellier, France

## ABSTRACT

**Objective:** A review of the literature was conducted for incidence, outcomes, and risk factors for distal stent graft-induced new entry (SINE) after thoracic endovascular aortic repair (TEVAR) of aortic dissection.

**Methods:** The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

**Results:** Seven articles reporting on 1415 patients with thoracic aortic dissection undergoing TEVAR without supplemental distal bare stenting were included. In this cohort, 86 patients were treated for a residual type A aortic dissection and 1329 for a complicated type B aortic dissection. Distal SINE occurred in 112 patients (7.9%). The mean time to identification of distal SINE was  $19 \pm 7$  months. The incidence of distal SINE after TEVAR for type B aortic dissection differed on the basis of whether it was a chronic or acute dissection repair and was, respectively, 12.9% (43/331) and 4.3% (12/273). Successful secondary interventions were performed in 54% of the patients. All the studies analyzing the relationship between distal stent graft oversizing and incidence of distal SINE reported a significantly higher rate of SINE with oversizing.

**Conclusions:** The successful management of complicated descending thoracic aortic dissections by TEVAR is well established. Whereas distal SINE is relatively frequent, if it does occur, the complication can generally be treated with additional TEVAR without a poor outcome. The main determinant of SINE seems to be excessive distal oversizing.

**Keywords:** Thoracic aorta; Aortic dissection; Stent graft; TEVAR; Aorta

The care of patients with aortic dissection continues to be one of the most formidable challenges faced by cardiovascular specialists. For uncomplicated cases, best medical therapy remains the “gold standard.” The modern management of complicated cases has largely shifted to thoracic endovascular aortic repair (TEVAR) because of the decrease in early morbidity and mortality. There are nevertheless ongoing anxieties about how these stent grafts will perform in the longer term. Stent graft-induced new entry (SINE) was previously defined as a “new tear caused by the stent graft itself, excluding those created by natural disease progression or any iatrogenic injury from endovascular manipulation.”<sup>1</sup> The definition of this potentially fatal condition includes tears at both the proximal and distal margins of the graft. SINE

is increasingly being observed after TEVAR, especially for Stanford type B dissections.<sup>1</sup> The principal sequela of concern for proximal SINE is retrograde type A dissection. Distal SINE could develop into a patent false lumen with subsequent aneurysmal expansion and possible rupture. We have already reported the incidence, mechanism, and factors predictive for retrograde aortic dissection.<sup>2,3</sup> Distal SINE was first reported by Kato et al<sup>4</sup> in 2001. The aim of this study was to investigate the incidence, mechanism, and predictive factors for distal SINE.

## METHODS

**Search strategy.** All studies published within a 16-year period reporting on risk factors for distal SINE after TEVAR for thoracic aortic dissection were identified through a review of the literature. The Embase, MEDLINE, and Cochrane databases for the period of January 1994 to May 2017 were searched for the keywords “SINE” or “distal stent graft-induced new entry” or “new entry” or “stent graft-induced new entry.” Only English-language articles were included. An additional manual review of references in the identified original papers and reviews was also performed.

**Study selection.** Studies were considered for inclusion and further review on the basis of the following criteria: articles reporting distal SINE after TEVAR for thoracic aortic dissection, excluding cases with supplemental distal bare stenting at the primary operation; articles

From the Department of Thoracic and Cardiovascular Surgery, Hôpital A de Villeneuve<sup>a</sup>; and the CHU Montpellier, PhyMedExp, Université de Montpellier, INSERM, CNRS.<sup>b</sup>

Author conflict of interest: none.

Correspondence: Ludovic Canaud, MD, PhD, Service de Chirurgie Vasculaire et Thoracique, Hôpital A de Villeneuve, 191 av Doyen Gaston Giraud, 34090 Montpellier, France (e-mail: ludoviccanaud@hotmail.com).

**Table I.** Study characteristics

	No. of patients	No. of patients with SINE	Type of study	Mean follow-up	Lost to follow-up
Dong et al <sup>1</sup>	650	7	Retrospective	–	None reported
Pantaleo et al <sup>6</sup>	108	30	Retrospective	36.1	None reported
Huang et al <sup>7</sup>	24	14	Retrospective	36	None reported
Jánosi et al <sup>8</sup>	144	9	Retrospective	47.5	None reported
Feng et al <sup>9</sup>	311	8	Retrospective	27.9	None reported
Jang et al <sup>10</sup>	79	17	Retrospective	52.7	None reported
Weng et al <sup>11</sup>	99	27	Retrospective	25	None reported

SINE, Stent graft-induced new entry.

reporting the incidence of distal SINE within a unit's total experience of TEVAR for aortic dissection; and articles analyzing risk factors for distal SINE. Studies containing duplicate data were excluded. Studies with the most recent or the highest quality documentation from the same authors were used for analysis.

Regarding the use of a composite device design (provisional extension to induce complete attachment [PETTICOAT] technique), which includes an uncovered infradiaphragmatic aortic stent in addition to standard TEVAR, there is no evidence that extended coverage of the descending thoracic aorta is needed to restore distal perfusion. As this is not first-line therapy for patients with thoracic aortic dissections, we did not include this approach in our study.

**Data extraction.** Data were extracted regarding indication for TEVAR (residual type A aortic dissection; complicated type B aortic dissection, acute or chronic), interval between TEVAR and distal SINE, symptoms (back or chest pain), need for treatment, outcomes, risk factors (acute or chronic dissection, distal oversizing, angulation of the distal landing zone, taper ratio of the true lumen [(proximal landing diameter – distal landing diameter)/proximal landing diameter]), and number of stent grafts used. All the patients included in the computed tomography (CT) scan analysis were patients discharged from the hospital. SINE was more commonly observed in the residual type A patients (39.5%) compared with the acute complicated type B (5.8%). However, for acute complicated type B patients, because there is high mortality for these patients, this is probably a bias in the analysis of the incidence of SINE for aortic dissection. In the studies included, the type of device and whether it was tapered were reported without reporting the number of SINEs according to the type of device. If details of a variable were not explicitly stated in the manuscript, those patients had to be excluded from that segment of the analysis. The denominator reported in our analysis therefore corresponds to available data. Study quality was rated according to a formal checklist.<sup>5</sup>

## RESULTS

### Search results

The initial electronic search yielded 32 articles. After screening of titles and abstracts and additional searches by hand in accordance with the inclusion criteria, data from seven published studies was included in the analysis.<sup>1,6-11</sup>

### Study characteristics

From the seven articles, 1415 appropriate patients treated by TEVAR were identified (Table I). In this cohort, 86 patients were treated for a residual type A aortic dissection and 1329 for a complicated type B aortic dissection.

SINE is defined as a "new tear caused by the stent graft itself, excluding those created by natural disease progression or any iatrogenic injury from endovascular manipulation."<sup>1</sup> This definition was unanimously used in all the included manuscripts.

Follow-up regimen for all the series included was similar with at least CT angiography after TEVAR at discharge, at 6 months, and at 12 months and yearly thereafter. Randomized trials of TEVAR for dissection were not included in this study because they report the incidence of distal reintervention without clearly reporting whether distal reintervention was related to a distal SINE or a retrograde filling of the false lumen.

### Epidemiology

**Incidence of distal SINE.** Distal SINE occurred in 112 patients (7.9%). None of the patients had a combined proximal and distal SINE. Five of the seven studies reported Asian patients treated for aortic dissection (incidence of SINE, 6.2% [73/1163]; incidence of SINE for non-Asian patients, 15.4% [39/252]).

**Timing of distal SINE.** The mean time to discovery of distal SINE was 19 ± 7 months.

**Symptoms.** Distal SINE was symptomatic in 5% of the patients and observed as back or chest pain.<sup>1,5-10</sup>

**Treatment.** Medical treatment with optimal blood pressure control was achieved in all patients. Procedural interventions (open and endovascular) were undertaken in symptomatic patients or those with an increase in

**Table II.** Summary of distal stent graft oversizing and taper ratio of the thoracic aorta of patients with distal stent graft-induced new entry (SINE) after thoracic endovascular aortic repair (TEVAR) for management of aortic dissection

	Distal stent graft oversizing	Taper ratio of the thoracic aorta
Dong et al <sup>1</sup>	NA	NA
Pantaleo et al <sup>6</sup>	Multivariate analysis: odds ratio, 1.858; 95% confidence interval: 1.109-3.064; $P = .018$	NA
Huang et al <sup>7</sup>	Univariate analysis: $P = .021$	Univariate analysis: $P = .024$
Jánosi et al <sup>3</sup>	Univariate analysis: $P < .01$	Univariate analysis: $P < .05$
Feng et al <sup>9</sup>	NA	Multivariate analysis: $P < .05$
Jang et al <sup>10</sup>	Univariate analysis: $P = .04$	Multivariate analysis: $P < .01$
Weng et al <sup>11</sup>	Multivariate analysis: $P = .02$	Multivariate analysis: $P = .958$

NA, Not applicable.

the false lumen size. Surgical or endovascular repair was reported in six studies<sup>1,5,7-10</sup>; 54% (53/98) of the patients underwent secondary procedures, TEVAR in 98% (52/53) or open surgery in 2% (1/53).

**Outcomes.** Treatment success was determined by exclusion of the aortic aneurysm or pseudoaneurysm, relief of malperfusion, and disappearance of symptoms. Treatment was successful in all patients ( $n = 53$ ). Two patients died during follow-up after the secondary procedure (10 and 16 months). Cause of death was not reported for either.

### Risk factors of distal SINE

**Indication for TEVAR.** For residual type A aortic dissection treated by TEVAR, the incidence was 39.5% ( $n = 34$ ). For acute type B aortic dissection treated by TEVAR, the incidence was 5.8% ( $n = 78$ ). The incidence of distal SINE after TEVAR for type B aortic dissection relative to the time of intervention was reported in four studies<sup>1,5,7,9</sup>; it was chronic in 12.9% (43/331) and acute in 4.3% (12/273).

Statistical analysis investigating whether SINE was more common in acute or chronic dissection was reported in four studies.<sup>1,5,7,9</sup> There was no difference in three studies ( $P = .26$ ,<sup>5</sup>  $P = .053$ ,<sup>7</sup> and  $P = .739$ <sup>1</sup>), but distal SINE did occur more frequently in patients with chronic dissection in a single study ( $P = .032$ ).<sup>9</sup>

**Distal stent graft oversizing.** Oversizing was based on the known diameter of the stent graft used and the maximal diameter of the true lumen at the predicted level of the distal stent graft (Table I). The association between distal stent graft oversizing and the incidence of distal SINE was analyzed in five studies.<sup>6-8,10,11</sup> All the studies reported a significantly higher rate of SINE in patients with distal stent graft oversizing  $>20\%$ .

In the study of Dong et al,<sup>1</sup> the amount of oversizing was reported only for the proximal part of the stent graft. Pantaleo et al<sup>6</sup> looked for a threshold value beyond which there was a greater risk for development of SINE. Based on multivariate analysis, they identified that the risk increased significantly with prestening graft oversizing area with values of 3.5 or greater.

**Taper ratio of the thoracic aorta.** The taper ratio of the thoracic aorta is defined as (proximal landing diameter – distal landing diameter)/proximal landing diameter (Table II).

Relationship between taper ratio of the thoracic aorta and incidence of distal SINE was analyzed in four studies.<sup>7,9-11</sup> All studies except that of Weng et al<sup>11</sup> reported a significantly higher rate of SINE with high taper ratio of the thoracic aorta. Jang et al<sup>10</sup> reported that the cutoff values for the prediction of SINE after TEVAR were 26.1%, 48.0%, 40.8%, and 72.9% for maximal diameter, mean diameter, circumference, and area.

### DISCUSSION

TEVAR has become the standard treatment of complicated thoracic aortic dissections. Even if it is minimally invasive, complications associated with stent grafts remain. In addition, for patients with dissection, who tend to be younger than those with aneurysmal disease, durability is a significant consideration. Reports of de novo entry tears at both the proximal and distal stent graft edge after TEVAR for dissection are emerging.

The incidence of distal SINE is high (7.9%), and the mean time to identification was  $19 \pm 7$  months. Distal SINE was asymptomatic in most of the patients (95% [106/112]), emphasizing the need for long-term CT surveillance in this cohort. This complication can be treated in most of the cases by additional stent graft placement.

The occurrence of distal SINE after TEVAR is considered to result from a combination of aortic wall fragility and irritation caused by the stent graft. SINE is generally believed to develop in patients with acute aortic dissection, in which the wall is more fragile than in chronic aortic dissection.<sup>4</sup> However, our review of the literature did not identify statistically significant increases in SINE in acute dissections. As a matter of fact, only Jang et al<sup>10</sup> reported that distal SINE was significantly more frequent in patients with chronic dissection. One possible theoretical explanation is that the vessel wall in chronic dissections is more fibrotic and calcified and therefore less elastic and less able to remodel than in acute dissections. As a consequence, it is conceivable



that the “spring-back” force of the stent graft (like a spring, the stent graft has an inherent tendency to spring back to its initial straight status when deployed in the thoracic aorta) could injure the stiff intimal membrane.

All the studies reported a significantly higher rate of SINE in patients with distal stent graft oversizing >20%. However, stent graft oversizing of 20% falls within the instructions for use for standard of care. Even inside the instructions for use, we previously reported that the occurrence of retrograde type A aortic dissection was associated with device oversizing (each 1% oversizing increase above 9% led to an increase in odds ratio of retrograde type A aortic dissection by 1.14 [ $P < .0001$ ]).<sup>2</sup> Straight stent graft selection is usually based on proximal landing zone diameter. True lumen diameter at the distal landing zone is typically significantly less than the proximal. This leads to excessive oversizing and radial force distally. The important discrepancy of the true lumen with the proximal landing zone is studied using the taper ratio. The taper ratio of the thoracic aorta is defined as (arch diameter – distal true lumen diameter)/arch diameter. Xu et al<sup>12</sup> studied the taper ratio of the thoracic aorta in patients with type B dissection and found that it was significantly larger in acute and chronic dissection patients than in healthy people. This conceptually would explain why taper ratio of the thoracic aorta and the associated excessive distal oversizing are strongly linked to the risk of distal SINE. All the studies except that of Weng et al<sup>11</sup> reported a significantly higher rate of SINE in patients with high taper ratio of the thoracic aorta.

To decrease the rate of reintervention after TEVAR for aortic dissection, what is the best strategy to reduce SINE? The distal stent graft-true lumen diameter mismatch seems to be the most significant etiologically. To ameliorate this, a tapered stent graft should be selected for most patients with dissection. Unfortunately, the maximum taper of commonly available grafts is only 4 mm. Frequently, the true discrepancy between the landing zones is larger. An alternative approach therefore would be to reverse the conventional order of implantation. By deploying a narrower stent graft in the distal aorta first and a wider stent graft proximally second, a more significant taper can be achieved without type III endoleaks. In addition, the perfect stent graft would exert lower radial force and greater conformability. As the incidence of distal SINE after TEVAR for type B aortic dissection seems to be higher for chronic dissection, probably because the intimal membrane is thicker and more fibrotic, we believe that we should size the stent graft according to the phase of the dissection; we should rely on the maximum diameter of the aorta for acute dissection and the diameter of the true lumen for chronic dissection.

The incidence of distal SINE was extremely variable among the different studies for several reasons.

Huang et al focused on chronic aortic dissection, which seems to be associated with a higher rate of distal SINE. Dong et al, reporting a distal SINE rate of 0.1%, had limited mean distal oversizing of  $13\% \pm 4.5\%$  compared with Jang et al, who had an incidence of 21.5% with mean distal oversizing of  $47.1\% \pm 32.9\%$ .

These differences may be highlighting the risk factors for distal SINE but must also be acknowledged as possible bias in this review. Placement of a restrictive bare stent has also been reported by Feng et al<sup>9</sup> as an adjunct to TEVAR, aiming to reduce the incidence of distal SINE. The distal bare stent is used to ameliorate the discrepancy in diameter between the healthy proximal landing zone and the narrow compressed distal true lumen that the stent graft is forced to accommodate. They reported a lower incidence of distal SINE compared with standard TEVAR with this strategy (0% vs 2.9%;  $P = .033$ ). This approach could be proposed for patients at high risk for distal SINE. Careful long-term clinical and CT scan follow-up of these patients is mandatory.

We suspect that there was a predominance of Asian publications of distal SINE because of the greater use of endovascular treatment in patients with type B dissection in these countries compared with Western populations (69.6% vs 13.3%;  $P < .01$ ).<sup>13</sup> However, in included studies, additional factors such as surgical techniques and device implantations could be different and could also explain the difference in terms of incidence of SINE.

This review has several limitations. Although it is the only review to date on distal SINE after TEVAR for aortic dissection, the pooled results are weakened by the lack of standardization in reporting of patient-specific data and end points. We could not report whether SINE was intentional (distal oversizing or ballooning with the intent to close off the false lumen completely) or unintended. We could not report the location within the aorta where SINE occurred. No studies of uncomplicated type B dissection patients who suffered from SINE were included. Residual type A dissections were combined with complicated acute and chronic type B dissections. This combination can be a bias in the interpretation of the data. Balloon dilation and the use of stent grafts with open-cell stents or active fixation at the distal margin were not reported. This could be an additional factor of distal SINE. Furthermore, we specifically focused in the review on incidence, outcomes, and risk factors for distal SINE.

## CONCLUSIONS

The successful management of complicated descending thoracic aortic dissections by TEVAR is well established. Whereas distal SINE is relatively frequent, if it does occur, the complication can generally be treated with additional TEVAR without a poor outcome. The main determinant of SINE seems to be excessive distal oversizing.

## AUTHOR CONTRIBUTIONS

Conception and design: LC, LS, PA

Analysis and interpretation: LC, TG, JS, BO

Data collection: LC, TG, JS

Writing the article: LC, TG, JS, BO

Critical revision of the article: LC, TG, JS, BO, LS, PA

Final approval of the article: LC, TG, JS, BO, LS, PA

Statistical analysis: LC, BO

Obtained funding: LC, PA

Overall responsibility: LC

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