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Venous stent patency may be affected by collateral vein lumen size

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Abstract

Purpose: Deep venous thrombosis causes blood flow deviation. It is hypothesized that with stent placement, developed collateral veins become redundant. This article evaluates the relation between the surface area of the collaterals and stent patency.

Methods: The azygos and hemiazygos veins were identified and the largest surface area was measured at thoracic level. Patency rates of stented tracts were evaluated and related to collateral vein lumen size.

Results: The vena cava occlusion and the azygos and hemiazygos vein surface area measurements were positive and statistically significant related (OR 1.01, 95% CI 1.003−1.019, $p = 0.004$) respectively (and OR 1.007, 95% CI 1.001−1.013, $p = 0.004$). An azygos surface area measurement of 23 ($p < 0.001$) and hemiazygos surface area measurement of 40 ($p = 0.008$) was shown as cut-off point related to higher occlusion rates.

Conclusions: The surface area of major venous collateral pathways seems to be related to stent occlusion in deep venous interventions.

Keywords

Deep vein thrombosis, endovascular treatment, post-thrombotic syndrome

Introduction

Deep venous thrombosis (DVT) is quite common and causes blood flow deviation in the venous system.[1,2] Pathophysiological changes after a DVT result in alternative drainage depending on the degree of recanalization. This venous recanalization, with vein wall fibrosis and synechiae formation, is a complex process in which many factors seem to play a role. When normal anatomical routes become chronically affected due to these post-thrombotic synechiae and vein wall fibrosis,[3–6] collateral veins are burdened with increased blood flow. Specifically, in caval vein obstruction, the azygos and hemiazygos, gonadal, spinal or abdominal veins have been described as predominant collaterals.[7,8] Normally, the azygos and hemiazygos veins are responsible for draining the thoracic wall and upper lumbar region via posterior intercostal veins. After post-thrombotic changes of the inferior caval vein, the azygos and hemiazygos veins become more important for blood drainage.[8] The recognition of these collateral pathways as well as the extent of acute and chronic obstructions can be evaluated by means of magnetic resonance venography (MRV), computed tomography, duplex ultrasound (DUS) and phlebography.[9–11]

More extensive DVT, involving not only the inferior caval vein but also the iliac (cavo-iliac) tract, can obstruct the outflow of the whole leg.[12] Subsequently, patients are more prone to develop complaints like edema and pain related to the post-thrombotic syndrome (PTS).[13,14] Severe cases of PTS are less responsive to conservative treatment and require more extensive percutaneous

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venous recanalization with trans-luminal angioplasty (PTA) and stent placement.[15] Studies have shown favorable clinical outcomes[16] with occlusions of the inferior caval and iliac veins to be the most challenging cases to treat. Secondary patency rates up to 93% have been described, whereas primary patency rates were 53%.[17]

It is hypothesized that with PTA and stent placement, developed collateral veins become redundant when the normal physiological route is restored. For example, a restored inferior caval vein will inevitably mean that enlarged azygos and hemiazygos collateral veins would become less important. However, the hemodynamic importance of collateral pathways and their effects on stent patency after an intervention has not yet been investigated. In an effort to explore various explanations for stent failure, the collateral veins of treated patients were reanalyzed on preoperative MRV scans.

Specifically, the aim of this article was to evaluate the relation between the collateral vein lumen size of the azygos and hemiazygos collaterals and stent patency.

Methods

This research was approved by the Ethical Committee of Maastricht (METC 16-4-183). All eligible patients treated for post-thrombotic (cavo) iliofemoral deep venous obstructions between 2012 and 2015 were evaluated. All patients experienced venous complaints and/or signs interfering with daily activities. Venous complaints and signs were defined as pain interfering with daily activities, and/or clinical signs classified according to the CEAP classification. Additionally, venous claudication was scored and regarded as a clinical complaint to perform deep venous treatment. Subjects treated for an acute thrombosis were excluded as natural recanalization did not occur and it was assumed that collateral veins would not have had ample opportunity to develop (n=8). When the azygos or hemiazygos veins could not be identified with certainty, the subject was excluded (n=1). Also, subjects treated with novel anticoagulant therapy were excluded as its effect on stent patency has not yet been investigated into detail (n=15 of which eight subjects had an occlusion somewhere in the follow up period). With these exclusion criteria, 199 patients were eligible for analysis.

Baseline characteristics like age, gender, number of DVTs and extensiveness of post-thrombotic changes were analyzed.

Magnetic resonance venography

A full description of the MR protocol has been described previously.[18,19] In short, a 1.5-T MRI system (Intera, Philips Healthcare, Best, The Netherlands) was used. The venous vasculature was imaged by a three-dimensional ultrafast gradient echo sequence (Ultrafast GE, THRIVE, Philips Healthcare) with fat suppression (spectral presaturation with inversion recovery, SPIR). Gadolinium based contrast (Gadobutrol; Gadavist, Bayer HealthCare, Berlin, Germany) was intravenously administered before scanning the subjects. A full lower extremity and abdominal scan was performed to ensure coverage of the lower veins up to the upper part of the inferior caval vein. The imaging evaluation was focused on the identification of chronic venous obstruction and related collateral patterns. Intraluminal synechiae with formation of collateral veins were considered as signs for post-thrombotic obstruction.

Based on MRV findings, the lower extremity post-thrombotic changes were subdivided into two scales. The first scale indicated obstruction of the common femoral and iliac veins. Subsequently, the involvement of the inferior vena cava resulted in the second scale.

The azygos and hemiazygos veins were identified and the largest found collateral vein lumen size was measured at a thoracic level (Figure 1). This collateral vein lumen size measurement was referred to as Region of Interest (ROI) and expressed as mm^2.

Treatment and follow up

A thorough description of the interventions has been described before.[18]

Iliac stents were positioned at least at the level of the common iliac vein (CIV) confluence, generally extending the spinous process. The iliac part was treated with a 18–14 mm diameter stent depending on the vein lumen after ballooning. The femoral vein was stented with 14–10 mm stents. For the caval obstructions, a sinus XL 24× 80–160 mm (Optimed, Ettlingen, Germany) was used as these stents were available in larger diameters. Bilateral treated subjects were stented in the caval vein. The iliac confluence was treated by either self-expandable stents inside the inferior vena cava (IVC) stent or by high radial force balloon-expandable stents at the same level. In both cases, bilateral iliac extensions were performed using nitinol stents. This second technique was developed to minimize stent related compression issues causing stent stenosis or occlusion.

Postintervention, all subjects were treated with anticoagulant therapy. Patients used Coumadin therapy with a target INR level between 3 and 4 for a minimum of 6 months.

During routine clinical follow up, complaints were evaluated and entered into a digital database. A DUS was performed to analyze the stent patency and possible stent related complications. This DUS evaluation was performed before discharge, at 2 weeks, 6 weeks, 3 months, 6 months, 12 months postintervention and annually thereafter.

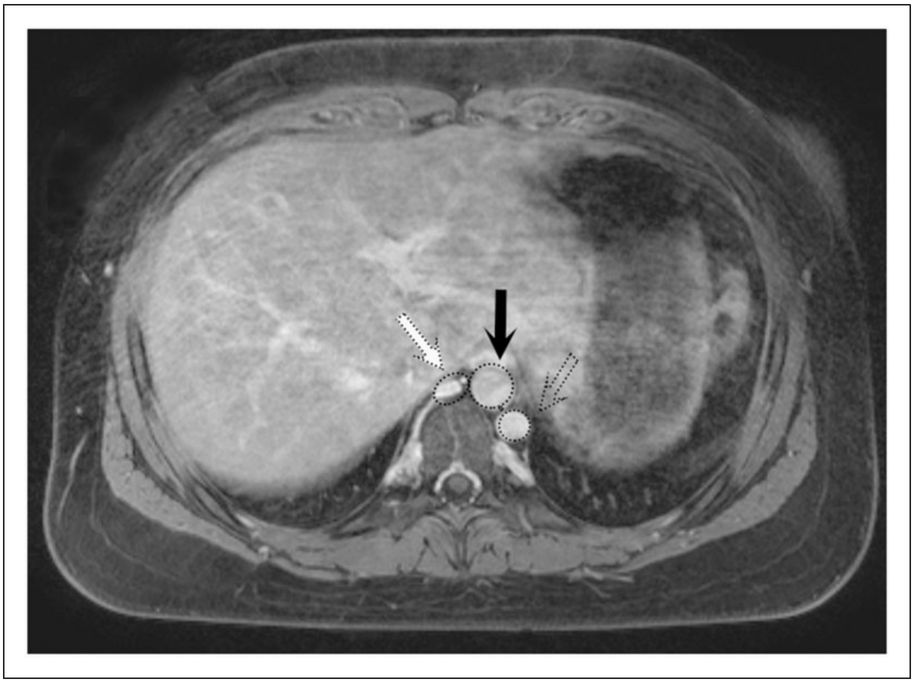

Figure 1. Example of ROI measurement at thoracic level.
ROI: Region of Interest; White arrow: azygos vein; black arrow: aorta; Grey arrow: hemiazygos vein.

Primary patency was scored as open stents with adequate venous flow and flow out of stenosis requiring any additional intervention. All subjects with an occlusion during the follow up period, were included in the secondary patency group. A thrombolysis with additional stenting and an arterio-venous fistula was performed when the patient experienced recurrent or new venous complaints. In patients without clinical complaints despite stent obstruction or an occlusion existing more than 3 weeks, this therapy was waived.

Statistics

The Shapiro–Wilk test was used to test the normality of the distribution. Continuous, normally distributed data were presented as a mean with their standard deviation. Non-normally distributed interval data were presented with lowest and highest scores. Categorical data were presented as frequencies and percentages.

The Spearman correlation coefficient (r) was used to inspect relationships between continuous variables. Logistic regression univariate analysis was used to measure the odds ratio (OR) between the measured collateral vein lumen size and the occlusion of stents. To show the distribution of collateral vein lumen size measurements and occlusion of stents, a ROC curve was performed. The distribution of vein collateral vein lumen size measurements was categorized and differences were compared using a chi-square test.

Table 1. Demographics.

Age, yr mean ± SD, range	43.2 ± 12.7 (17–75)	
Gender N, %		
Male	66	33%
Female	133	67%
BMI (median, IQR)	27.1 (23.5–30.2)	
Coagulopathy	44/148	30%
PTS scale N, %		
Scale 1	176	88%
Scale 2	23	12%
Number DVT's		
1	145	73%
>1	54	27%
Time from DVT, mnth median, IQR	51 (22–134)	

PTS: post-thrombotic syndrome; Yr: year; N: number; DVT: deep venous thrombosis; mnth: month.

An α of < 0.05 was considered to be statistically significant. Data were analyzed using IBM SPSS statistics v23.0 (IBM Corporation, Armonk, NY, USA).

Results

Table 1 shows the demographics of all included patients. The mean age was 43.2 years (±12.7, range

17–75) and 67% of the patients were female. About 27% of the patients had more than one deep vein thrombosis in the treated leg. With a median follow up of 14 months (8–27), the primary patency of this cohort was 80%. An occlusion occurred in 20% somewhere during the follow up period. After a median follow up of 14 months, a total of 10% had an occluded stent.

A median of two stents were used to treat the post-thrombotic lesions. In 138 (70%) patients, this was performed using a Sinus Venous stent. In 23 (12%) patients, an SXL was used for the caval obstruction and Andra or Obliquus stent for the iliac confluence. Furthermore, SXL stents (n = 31, 15.5%), Veniti stents (n = 3, 1%), Zilver vena (n = 3, 1%) or Venovo (n = 1, 0.5%) stents were used.

Collateral vein lumen size measurements and post-thrombotic involvement of the inferior caval vein

The median score for azygos collateral vein lumen size was 20.5 mm^2 (diameter 6.5 mm , IQR 14–32) and the median score for the hemiazygos collateral vein lumen size was 33.5 mm^2 (diameter 10.5 mm, IQR 21–51).

Twenty-three patients (12%) had post-thrombotic fibrosis in the inferior vena cava on the pre-interventional MR scan. The univariate relationship between the vena cava occlusion and the collateral vein lumen size measurements was positive and statistically significant for the azygos vein (OR 1.01, 95% CI 1.003–1.019, p = 0.004). Also, hemiazygos collateral vein lumen size measurements were statistically significant higher in patients with involvement of the vena cava compared to patients without the involvement of the vena cava (and OR 1.007, 95% CI 1.001–1.013, p = 0.004).

Time to latest DVT and collateral vein lumen size

As collateralization takes time and recanalization can occur up to 12 months after a DVT,[20] the time between the latest known DVT event and MR scan was evaluated. The median time between the latest DVT and the MRV scan was 51 months (IQR 22–134). To analyze the relation between the timespan and the collateral vein lumen size, a correlation analysis was performed. A Spearman correlation test did not show a significant correlation for both the ayzgos or the hemiazygos vein (r −0.010, p 0.89; r −0.036, p 0.61, respectively).

Also, the number of DVTs before stenting and the relation to enlarged collateral vein lumen size measurements was analysed. This analysis did not show a statistical significant difference for the azygos or hemiazygos vein (p = 0.48, p = 0.67, respectively).

Table 2. Azygos ROI and diameter measurements related to stent patency.

ROI (diam) azygos	Patent (N, %)	Occluded (N, %)
<15 (<4.8)	51 (94)	3 (6)
15–20 (4.8–6.4)	43 (94)	3 (6)
21–32 (6.5–10.2)	40 (74)	14 (26)
>32 (>10.2)	24 (53)	21(47)

ROI: Region of Interest; N: number; Diam: diameter.

Table 3. Hemiazygos ROI and diameter measurements related to stent patency.

ROI (diam) hemiazygos	Patent (N, %)	Occluded (N, %)
<21 (<6.7)	47 (87)	7 (13)
21–33 (6.7–10.5)	41 (89)	5 (11)
34–50 (10.6–15.9)	40 (77)	12 (23)
>50 (>15.9)	30 (64)	17 (36)

ROI: Region of Interest; N: number; Diam: diameter.

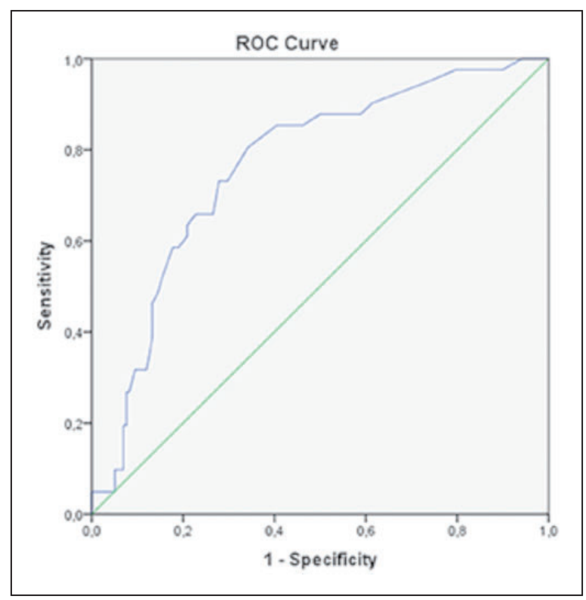

Figure 2. A ROC analysis for occurrence of stent occlusion and ROI of the azygos vein. An area under the curve (AUC) of 77% (95% CI 0.69–0.84), with increasing azygos vein ROI, a higher number of stent occlusions is seen.
ROI: Region of Interest.

Collateral vein lumen size measurements and occlusion of stents

The collateral vein lumen size measurements were subdivided into categories to analyze its relation

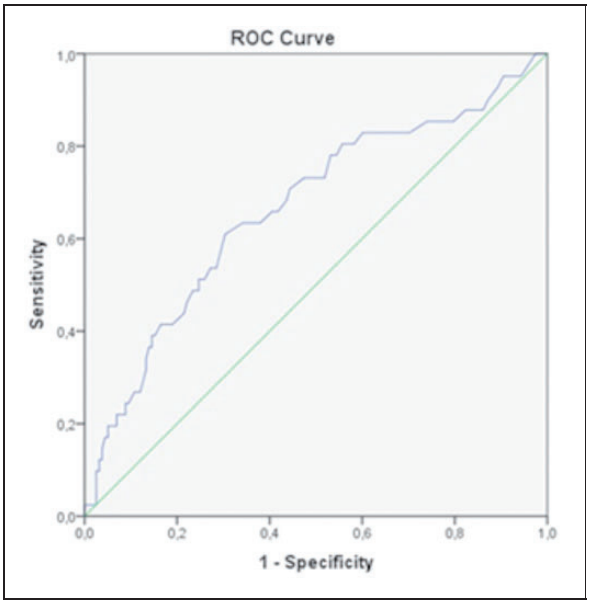

Figure 3. A ROC analysis for occurrence of stent occlusion and ROI of the hemiazygos vein. An area under the curve (AUC) of 67% (95% CI 0.57–0.77) with increasing hemiazygos vein ROI, a higher number of stent occlusions is seen.
ROI: Region of Interest.

to stent occlusion. Table 2 shows the collateral vein lumen size measurements of the azygos vein related to stent patency. A collateral vein lumen size measurement of 23 mm^2 (diameter > 7.3 mm) was shown as the cut-off point related to higher occlusion rates ($p < 0.001$).

Table 3 shows the collateral vein lumen size measurements of the hemiazygos vein related to stent patency. A collateral vein lumen size measurement of 40 (diameter > 12.7) was shown as the cut-off point related to higher occlusion rates ($p = 0.008$).

A ROC analysis was performed to discriminate between the occurrence of stent occlusion. For the azygos vein, an area under the curve (AUC) of 77% (95% CI 0.69–0.84) (Figure 2) and for the hemiazygos vein, an AUC of 67% (95% CI 0.57–0.77) were found (Figure 3).

Univariate analysis of variance on occlusion rate and azygos collateral vein lumen size showed a significant effect when controlled for BMI, age, gender and coagulopathy ($p < 0.001$). When controlled for hemiazygos collateral vein lumen size, the effect of azygos size still remained. No significant effect of hemiazygos collateral vein lumen size and stent occlusion was found when controlled for BMI, age, gender risk of thrombosis ($p = 0.78$).

Type of obstruction and occlusion of stents

In order to analyze whether there was a relation between the extent of the post-thrombotic changes and the risk of stent occlusion, a Pearson correlation test was performed. In 88% of the patients, a scale 1 was found indicating post-thrombotic changes up to and thus excluding the vena cava. The risk of stent occlusion was not statistically significant related to the extent of post-thrombotic changes ($p = 0.89$). Furthermore, when the number of DVTs was dichotomized into one or multiple events, this was not significantly related to the occurrence of stent occlusion ($p = 0.41$).

Discussion

Recanalization after a DVT results in the development of intraluminal synechiae or fibrotic vessels.[6] Therefore, the veins are incapable of normal expansion and thus limited in transporting blood especially when volumes increase during exercise. Although collateral veins function as detours, they seem to be an inferior conduit and are less able to adopt the function of non-diseased veins.[21] Subsequently, the main goal of venous stenting is to restore the original pre-thrombotic venous anatomy as to transport blood more effectively and reduce clinical complaints. It is expected that the main volume of flow should pass through the stented segments. However, competitive outflow routes might diverge the blood away from the stents and as a consequence increase the risk of thrombus formation and thrombotic stent occlusion. This fact has been described by Neglen and Raju explaining that the presence of collaterals could be an indicator of more severe stenosis, but significant stenosis can also be apparent without collateral formation.[22] Since thrombotic stent occlusion may result in the recurrence or worsening of clinical complaints, the aim was to search for a predictor of stent occlusion in order to provide more realistic expectations for physicians and patients. As a consequence, the relation between stent patency and the collateral vein lumen size of the azygos and hemiazygos veins were evaluated. The results presented, show that patients with a larger collateral vein lumen size were more prone to stent occlusion.

According to the literature, the azygos and hemiazygos veins are responsible for venous blood flow towards the heart in patients with a caval obstruction.[7,8] Accordingly, the results in this article show the importance of the azygos and hemiazygos veins when properly quantified according to their lumen size. This means that physicians could focus on the analysis of particular collateral pathways before contemplating interventional treatment. As a consequence, the chance of stent occlusion might be predicted and provide a more realistic expectation for patients. The probability of stent occlusion based on the azygos and hemiazygos collateral vein sizes is shown in the ROC curves with an AUC of 74% and 67%, respectively. To make a precise discrimination, a high sensitivity and specificity would be ideal. Consequently, a cut off value with a high sensitivity should be determined to select those patients at risk for a stent occlusion. With the results of this study, a clear cut-off factor could not be pointed out, as there are subjects with high ROIs without occlusion and subjects with low ROIs with thrombotic stent occlusions. However, a significant increase in stent occlusion was seen in azygos collateral vein lumen size measurements above $23\,mm^2$ (diameter $> 7.3\,mm$) and hemiazygos measurements above $40\,mm^2$ (diameter > 12.7).

As stent failure after deep venous reconstruction seems to be a multifactorial process, some other factors were analyzed to exclude them as contributing factors in thrombotic stent occlusion. To examine whether the recovery time after a DVT had a significant effect on the collateral vein lumen size measurements, a correlation analysis was performed. Since no statistical significant difference was found, it is fair to conclude that the collateral vein lumen size is not correlated with timespan between initial DVT and treatment. Furthermore, the number of DVTs did not seem to be related to higher collateral vein lumen size measurements. Moreover, with a pre-interventional DVT recurrence of 27% it may be suggested that these patients had a higher predisposition for thrombotic stent occlusion.[23] However, no significant difference in stent failure after multiple DVTs could be found ($p = 0.41$).

Previous literature describes that longer stented tracts are more prone to stent occlusion.[23–25] This might be caused by a limited flow in the venous system combined with a high thrombogenicity to stent material. However, in this study, no significant evidence ($p = 0.89$) was found for the rate of stent occlusion and extent of diseased vein segments.

The results in this study might postulate about implications for pre-procedural imaging, treatment strategies and post-procedural strategies. Currently, cross-sectional imaging is used to determine the extent and severity of deep venous obstruction. Moreover, it might distinguish patients fit for a simple endovascular procedure and those who are more likely to be favored by a more extensive intervention. However, based on the results that indicate a probable role for collateral vein diameter and success of deep venous intervention, future research should focus on this item into more detail.

Although it was not possible to determine a single cut-off value above that all interventions would fail, a trend could be shown. In practice, it should be wondered, when not treating a patient due to the high risk of thrombotic stent occlusion outweighs possible intervention related complications. Furthermore, it should be questioned whether patients with higher ROIs should be treated in a different manner than patients with smaller ROIs. Theoretically, covered stents, overlaying at the orifice of the prominent collaterals, might be an adequate alternative to force the flow through the stents. Furthermore, several other options like embolization of large collaterals or rheological endeavours might seem effective as well, although occluding the collaterals might as a consequence increase the clinical complaint after stent occlusions due to other causes. Therefore, this research does not support any such procedure as long as the exact pathophysiological mechanisms are scrutinized.

Furthermore, with stent occlusion being such a multifactorial process, multiple probable confounding factors should be eliminated as much as possible. Although the extent of post-thrombotic changes did not relate to statistically significant differences in stent patency, this should be included in future trials.

Study limitations

Due to the retrospective analysis of this research, some factors cannot be taken into account. One of which, the anticoagulation is an important issue especially during the first few weeks as to prevent thrombotic stent occlusion. In the Netherlands, specialized institutes are responsible for the regulation of INR levels. Since specialized thrombosis institutes regulate the INR levels, INR fluctuations between follow up visits are not detected by the treating physician. A cohort analysis is currently started to focus on this limitation and examine the fluctuations in relation to stent occlusion.

Besides, there are few stent occlusions in this cohort which may increase some bias. Other potential confounding factors like in- and outflow, iliac confluence stenting technique, venous pressure measurements, diameter of stents, pelvic collaterals and technical aspects, should be taken into account in a prospective trial. Additionally, MR evaluation after stenting should be performed to follow collateral vein lumen sizes after stenting.

Likewise, the diversion and percentage of blood flow to guarantee patent stents, remain a difficult part to analyze since a quantified parameter is still lacking. If these parameters are quantified and compared before, during and after stenting they should provide valuable information about the future outcome. Since these factors are currently unavailable, additional images techniques do show the importance of collaterals as presented in this article and should be focused into more detail.

Conclusion

The collateral vein lumen size of major venous collateral pathways seems to be related to stent occlusion in deep venous interventions. This preliminary observation might have a significant impact on pre-interventional imaging, treatment strategies and post-interventional protocols. Moreover, these findings may guide future research into the significance of collaterals in deep venous obstructions.

Declaration of Conflicting Interests

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Ethical approval

This study was approved by the medical ethical committee of Maastricht University (reference number METC 164183).

Guarantor

Not applicable.

Contributorship

TV; study design, data collection, data analysis, writing, reviewing article. SD; study design, data collection, data analysis, reviewing article. IT; study design, reviewing article. RdG; study design, reviewing article. CW; study design, reviewing article.

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