

■ Original Article

Perivascular administration of hyaluran-cyanoacrylate complex gel for deep venous reflux

Derin venöz reflü tedavisinde hyaluran-siyanoakrilat kompleks jelin perivasküler uygulaması

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Abstract

Aim: Deep venous insufficiency is an important health issue affecting the population worldwide. In this study we aimed to assess the effectiveness and safety of a novel antireflux treatment procedure in patients with primary deep vein insufficiency.

Material and Methods: Between October 2016 and December 2018, 81 valvular leak operations consisting of perivenous hard gel injection were performed in 81 patients with primary deep venous insufficiency. The clinical symptoms of the patients were between C3-C6 according to the CEAP clinical classification. Venous insufficiency associated with only one deep venous valve was verified with Doppler ultrasonography. Patients were assessed with physical and ultrasound examination on the follow-up visits, which were achieved on the third day and at the first, sixth, and twelfth months. The nonexistence of reflux in the treated valve level was defined as the success of the procedure. Any reflux, which lasted 0.5 seconds or more, was regarded as a lack of success.

Results: The ages of the patients ranged between 32 and 78. All the patients had deep venous insufficiency. The follow-up could be achieved in all the patients. The mean volume of the gel administered was 2.4 ± 0.9 ml. The mean procedure duration was 22.3 ± 8.9 (range 14–42) minutes. The procedures could be performed successfully in all of the patients confirmed perioperatively and on the third day of follow-up with the elimination of reflux. The sixth-month follow-up, with the same vein diameter after the treatment without any reflux, revealed the same findings as to the first-month follow-up. The treatment was not associated with any significant morbidity or mortality. The VCSS decreased significantly when preprocedural and twelfth-month VCSS were compared as 21.8 ± 4.8 and 3.8 ± 0.7 , respectively ($p < 0.001$).

Conclusions: Treatment of venous insufficiency with the novel hard gel injections of hyaluronic acid and n-butyl-cyanoacrylate seems safe, effective, and feasible confirmed with early and midterm follow up results.

Keywords: Venous insufficiency; Femoral vein; Venous valves; Lower extremity; N-butyl-cyanoacrylate.

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Öz

Amaç: Derin venöz yetmezlik dünya çapında popülasyonu etkileyen önemli bir sağlık sorunudur. Bu çalışmada primer derin ven yetmezliği olan hastalarda yeni bir antireflü tedavi prosedürünün etkinliğini ve güvenilirliğini değerlendirmeyi amaçladık.

Gereç ve Yöntemler: Ekim 2016-Aralık 2018 tarihleri arasında primer derin venöz yetmezliği olan 81 hastaya perivenöz sert jel enjeksiyonundan oluşan 81 venöz valvüler kaçak operasyonu uygulandı. Hastaların klinik semptomları CEAP klinik sınıflamasına göre C3-C6 arasındaydı. Sadece bir derin venöz kapakla ilişkili venöz yetmezlik Doppler ultrasonografi ile doğrulandı. Hastalar 3. gün, 1., 6. ve 12. aylarda yapılan kontrollerde fizik muayene ve ultrasonografi ile değerlendirildi. Tedavi edilen kapak seviyesinde reflü olmaması işlemin başarısı olarak tanımlandı. 0,5 saniye veya daha uzun süren herhangi bir reflü, başarısızlık olarak kabul edildi.

Bulgular: Hastaların yaşları 32 ile 78 arasında değişiyordu. Hastaların tamamında derin ven yetmezliği vardı. Takip tüm hastalarda sağlanabildi. Uygulanan jelin ortalama hacmi $2,4 \pm 0,9$ ml idi. Ortalama işlem süresi $22,3 \pm 8,9$ (dağılım 14-42) dakikaydı. Hastaların tamamında işlem başarıyla uygulandı ve perioperatif olarak ve takibin 3. gününde reflünün ortadan kalkması ile doğrulandı. Altıncı ay kontrolünde, reflü olmaksızın tedavi sonrası aynı damar çapı ile birinci ay kontrolü ile aynı bulgular saptandı. Tedavi, herhangi bir önemli morbidite veya mortalite ile ilişkili değildi. VCSS, işlem öncesi ve 12. ay VCSS karşılaştırıldığında sırasıyla $21,8 \pm 4,8$ ve $3,8 \pm 0,7$ olarak anlamlı olarak azaldı ($p < 0,001$).

Sonuçlar: Venöz yetmezliğin yeni sert jel hyaluronik asit ve n-bütül-siyanoakrilat enjeksiyonları ile tedavisi güvenli, etkili ve uygulanabilir görünmektedir ve erken ve orta vadeli takip sonuçları ile doğrulanmıştır.

Anahtar Kelimeler: Venöz Yetmezlik; Femoral ven; Venöz kapaklar; Alt ekstremitte; N-bütül-siyanoakrilat.

Introduction

Chronic venous insufficiency (CVI) is a condition that impairs patients' quality of life with specific clinical manifestations and symptoms, such as edema, ulcers, and pain. Deep veins in the affected limb can be involved in the disease with reflux in the venous valves, termed deep venous reflux (DVR). The treatment in DVR is mainly compression therapy, but in severe cases, surgery or interventional therapies can be options [1-3].

Etiological classification of the DVR is performed using well-known CEAP classification, where "E" stands for etiology. The secondary reasons of DVR, as in post-thrombotic syndrome (PTS) or trauma (Es) are the most frequent types and seen in nearly 60-85% of cases [4,5]. The valve structure is injured due to inflammation and thrombosis in the vein, leading to a partial or total valve dysfunction. Hence, a direct valve repair is not an option for treatment [6]. On the other hand, attempts for reversal of the reflux by reversal of the dilated venous segment into normal diameters and approximation of the valvular structures may be an option in this particular group to prevent DVR. Such procedures were attempted surgically (7, 8) and with percutaneous means (3, 9).

The application of hard gel injections of hyaluronic acid and n-BCA (n-butyl-cyanoacrylate) over defective deep vein valves between the deep vein and muscle fascia, so called internal compression therapy (ICT) is a unique and novel treatment option [3]. By applying hard gel implants, the goal is to

approximate the vein valves to each other. The gel remains over the vein and can shift with the muscle pump helping the malfunctioning valves work appropriately. This paper aimed to verify the effectiveness and safety of internal compression therapy in patients with primary deep valve insufficiency (PDVI) during a single-session procedure.

Materials and Methods

Patient selection

From October 2016 to December 2018, 81 patients who suffered from primary deep venous insufficiency underwent valvular leak operations. Venous insufficiency was associated with only one deep venous valve. CEAP and Venous Clinical Severity Score (VCSS) classifications were used to categorize the patients. Only patients with CEAP clinical scores between C3-C6 were included in the study. The study's ethical approval was obtained (Number: 92198657). Following patient eligibility and obtaining written informed consent, the clinical and ultrasound (US) examinations were performed by a vascular surgeon and an unbiased radiologist.

Patients were assessed by duplex US scanning to verify the superficial, deep, and perforator veins' actual anatomy.

Duplex scanning was conducted in the standing position using the conventional method. Assessment of the reflux was performed using a cuff placed at the calf level, and afterward, the evaluation of the reflux was carried out in the supine position. CEAP, VCSS, and US findings were recorded.

Selection criteria

Deep venous reflux was seen in all patients with duplex scanning. The CEAP classification was Clinical classification 3-6 (C3-6), Etiologic classification was primary (Ep), Anatomic classification deep (Ad), and Pathophysiologic classification reflux (Pr) among patients. Of 81 patients, 53 had superficial/perforator reflux, and these patients were treated before the ICT intervention. Patients with ulcers had lesions that were resistant to standard therapies and superficial and/or perforator vein abolition procedures. The ulcers persisted for at minimum one year or had been recurring in the same interval of more than once, which implied that the ulcer had been existing for more than one year.

The exclusion criteria were advanced limited mobilization, thrombophilic syndrome, post-thrombotic etiology, history of deep vein thrombosis, contraindication to anticoagulant therapy, severe comorbidity, and eligibility for surgical treatments such as femoral transposition or valve transplant, and deep venous reflux <2 seconds [10-14].

Intervention technique

Local anesthesia was used for all procedures, and the interventions were done with the standard sterile method. With the extremity mildly flexed, the patient was positioned supinely before the procedure. The treatment goal is to decrease the diameter of the vein until the space among vein valves closes. Defective deep vein valve positions were verified under US. All the insufficiencies were detected in the suprasaphenous valves in common femoral veins, and the anatomical sites for injections were determined by US (Figure 1). The space between defective valves and the vein caliber were determined (Figure 2).

The ICT (Internal Compression Therapy) Paravalvular Leak Device (Invamed, Ankara, Turkey) mainly consists of two parts. The main part includes a gap-closing kit with a monitored mixing unit, administration unit, and two vials of hyaluronic acid and n-BCA. The distribution part of the device is a system with an aspiration and administration adapter, a distribution line, and 2 units of 6F, 11-cm cannulas (Figure 3). The access to the region between the muscle fascia and the deep vein was done using the Seldinger technique. The access was performed twice, one entry on each side, on opposite sides of the vein to administer ICT hard gel evenly across the deep vein. A 0.035", 45-cm guidewire was introduced and secured just over the deep vein after the access. The needles were removed, and 6F, 11-cm distribution system cannulas were introduced over the wire to both sides of the vein valve.

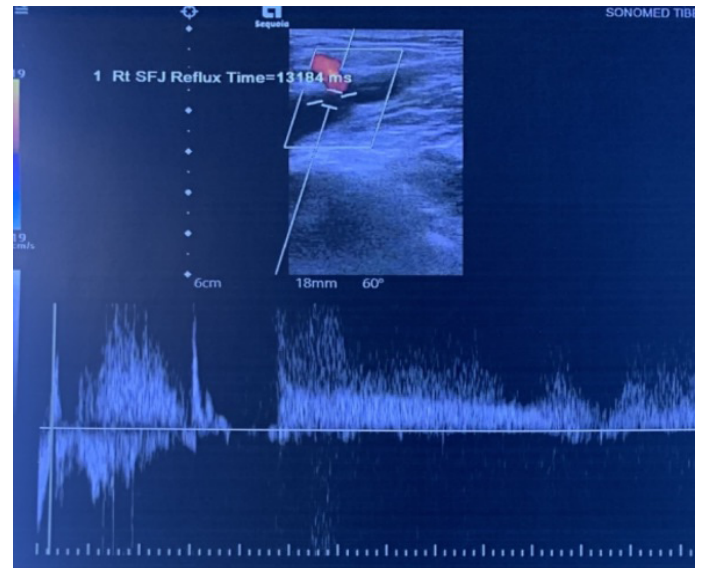


Figure 1: Preoperative doppler ultrasonography revealing reflux of saphenofemoral junction.

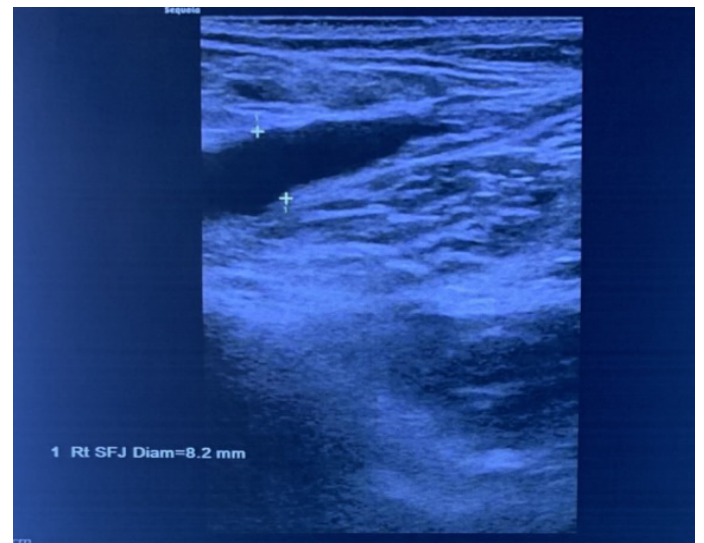


Figure 2: The preoperative saphenofemoral junction diameter on doppler ultrasonography.

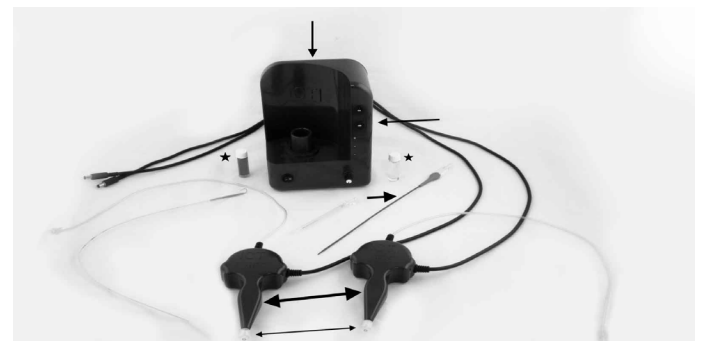


Figure 3: The Internal Compression Therapy (ICT) system. System is composed of a mix unit (down arrow), an injection unit (left arrow), vials containing hyaluronic acid and n-BCA (stars), aspiration and injection connectors (two-sided thin arrow), delivery lines and delivery ports (two-sided arrow), and two 6F-11 cm cannulas (right arrow).

Two separate 2-ml vials of hyaluronic acid and n-BCA come with the ICT kit. The hyaluronic acid and n-BCA were blended for 30 minutes with a preset program in the ICT device mixing unit prior to administering over the valves. The mixed vial was attached to the aspiration adapter while the cannulas were connected to the administration adapter. The ICT system administration unit was triggered and calibrated to the required administration rate. Under US, handled administration started, and the vein caliber reduced to the disparity between the vein caliber and the space between the valves (Figure 4). The aspiration was activated instantly to collect excessive gel if needed. After the space among valves was eliminated, manual compression was applied for 1-2 minutes to the injection site. Then, the valve function and reflux were documented with US (Figure 5). The administration of the hard gel was repeated if the reflux persisted. The cannulas were removed after verifying the competency of the valves. The compression stockings (20-30 mmHg) were utilized just after the procedure, and the patient was encouraged for prolonged use.

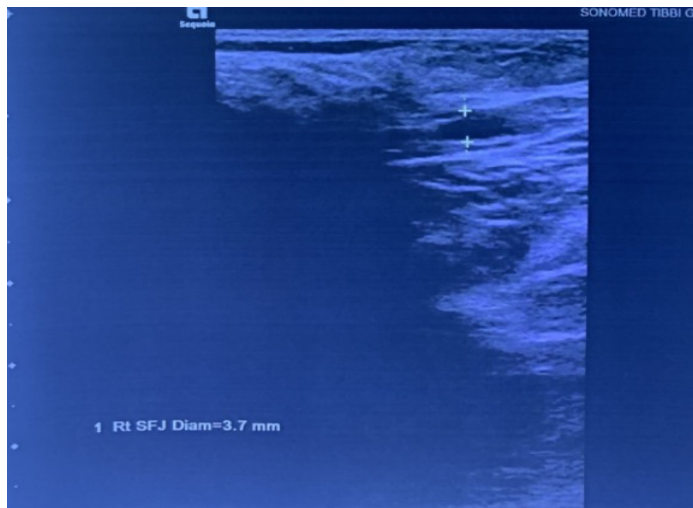


Figure 4: The postoperative saphenofemoral junction diameter on doppler ultrasonography.

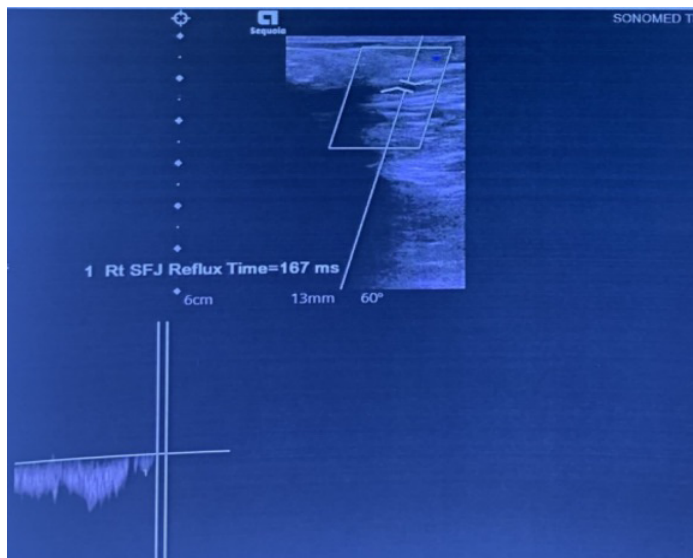


Figure 5: Postoperative doppler ultrasonography revealing reflux of saphenofemoral junction.

Follow-up

Patients were assessed with physical and US examination on the follow-up visits, which were achieved on the third day and at the first, sixth, and twelfth months. The success of the therapy was identified as a patent deep vein without reflux or with reflux, which is not exceeding 0.5 seconds.

Statistical analysis

Statistical analysis was carried out using the SPSS for Windows software package (ver. 22; SPSS Inc. Chicago, IL, USA). All variables were assessed using visual (histograms, probability plots) and analytical (Kolmogorov-Smirnov test) modes to decide if they were normally distributed. Continuous parameters are indicated as the means \pm SDs for normally distributed parameters and as medians with interquartile ranges for non-normally distributed parameters. Categorical parameters are described as numbers and percentages (n, %). Reference level alterations in VCSS were contrasted between control periods using paired t-test. Kaplan-Meier estimator was used for estimating the total removal of deep vein reflux. P-values <0.05 were assumed to be of statistical significance.

Results

A total of 81 patients (38 male, 43 female, median age: 54; range, 32 to 78 years) with deep venous insufficiency who had VCSS between 10-29 (mean: 21.8 ± 4.8) were enrolled in the study. The mean vein diameter at the valve level was 11.9 ± 2.7 (range 8.9-16.5) mm. The reflux was at least 3 seconds which reached up to 15 seconds (mean: 11.6 ± 3.6 sec) at the valve level. The distance between the valves ranged between 1.9-7.0 (mean: 3.8 ± 1.2) mm. There were 25 (31%) patients at C3, 21 (26%) patients at C4, 24 (30%) patients at C5 and 11 (13%) patients at C6 class according to the CEAP classification. In 43 patients the left leg was intervened where as in the remaining the right leg. Except one popliteal vein, femoral vein was the primary site of intervention. Patient demographics are provided in Table I.

The follow-ups were achieved in all the patients. The mean volume of the gel administered was 2.4 ± 0.9 ml. The mean procedure duration was 22.3 ± 8.9 (range 14–42) minutes. The procedure's achievement amounted to 100%, and just after the procedure and on the third day of follow-up, total elimination of reflux was confirmed. The sixth-month follow-up, with the same vein diameter after the treatment without any reflux, revealed the same findings as to the first-month follow-up. In two patients vein diameters were observed to be increased with a reflux less than 0.5 seconds at the twelfth-month follow-up, described in the study's success criteria.

Table 1: Demographic features of the patients.

	Mean ± Std (Mean)/ Preoperative	Mean ± Std (Mean)/ Postoperative	n (%)
Age (years)	54 ± 22.4 (range 32-78)		
Female gender			43 (53)
Male gender			38 (47)
Vein diameter at valve level (mm)	11.9 ± 2.7 (range 8.9-16.5)	3,9 ± 0,8 (range 2.3-7.5)	
Distance between valves (mm)	3.8 ± 1,2 (range 1.9-7.0)		
Reflux (sec)	11.6 ± 3.6 (range 3-15)		
Preoperative CEAP category			
C3			25 (31)
C4			21 (26)
C5			24 (30)
C6			11 (13)
Postoperative CEAP category			
C0			33 (41)
C1			33 (41)
C2			10 (12)
C3			3 (4)
C4			1 (1)
C5			1 (1)
VCSS (p<0.001)	21.8 ± 4.8 (range 10-29)	1,9 ± 1,49 (range 0-7)	
Right leg/Left leg			38/43(47/53)
Symptomatic improvement			75 (92)
Postoperative Deep Vein Thrombosis			-

The treatment was not associated with any significant morbidity or mortality. Minority of the patients experienced pain early after intervention which was controlled with non-steroid anti-inflammatory agents and completely disappeared in all patients by the end of 24 hours. No complications such as ecchymosis, skin pigmentation, hematoma, paresthesia, deep vein thrombosis, or pulmonary embolism were seen after the treatment. In a median interval of 10 (range: 3-18) weeks, all the patients exhibited complete ulcer recovery. The postprocedural caliber of the deep vein was 8.9±1.6 mm. After the operation, all patients had significantly improved VCSS. The preprocedural and twelfth-month VCSS were 21.8 ± 4.8 and 3.8±0.7, respectively (p<0.001). There were 33 patients at C1, 10 patients at C2, 3 patients at C3, 1 patient at C4 and 1 patient at C5 class according to the CEAP classification after 12 months.

Discussion

The current research provides one of the first experiences and preliminary results of the application of hard gel injections of hyaluronic acid and n-BCA (n-butyl-cyanoacrylate) over defective deep vein valves between the deep vein and muscle fascia with a novel equipment, the ICT (Internal Compression Therapy) Paravalvular Leak Device (Invamed, Ankara, Turkey), in the literature.

Yavuz et al. conducted the first study in deep venous insufficiency, which evaluated the clinical results of internal compression treatment. They concluded that the postprocedural outcomes were safe and sufficient. We also analyzed the early-term clinical results of this treatment modality in PDVI patients. The results of our study are consistent with the results published by Yavuz et al., which confirmed that for the management of deep venous insufficiency, the internal compression treatment is secure and extremely efficient [3]. During the 12-month monitoring, there were no significant adverse or toxic instances recorded. Until now, there are no mentioned toxic, carcinogenic, or mutagenic consequences of hyaluronic acid or n-BCA with vascular or nonvascular applications [15-18].

Valvuloplasty is rarely the treatment choice due to the feasibility, risks and benefits are discussed in clinical practice up to date. The efficacy of surgical approaches including valvuloplasty, axillary vein transfer, and dacron sleeve in situ are still under debate, and no definite management for deep venous insufficiency is formulated [19-21]. However, perivenous internal compression is easy to perform after a learning period with improved results. According to Ragg et al., hyaluronan (hyaluronic acid) in superficial venous insufficiency, together with sclerotherapy, is suitable to



compress veins. Hyaluronan compression was successful in reducing the diameter of the vein. Moreover, no complications were observed clinically in terms of physical examination and patient comfort during follow-up [9, 17]. N-butyl cyanoacrylate is also shown to be reliable and successful for intravascular use in patients with superficial venous reflux disease [22-26]. In addition to polymerization of the molecule when it interacts with blood, the binding effect of the n-BCA to the vein wall enhanced the collapse of the vein. The binding property of the n-BCA increases when it combines with hyaluronic acid, which is then stabilized by n-BCA over the intended vein segment.

The hard gel administration over the two sides of the vein was aimed to cover the vein's external surface circumferentially. This method permits forming a permanent exoskeleton over the vein, moving together with the muscle fascia, and taking advantage of the muscle pump. There is no fixed volume to be injected over the vein. The administered volume differs according to the patient's duplex US examination, where the distance between valve leaflets is measured. The aim is to provide competence of the valve leaflets.

Treatment of deep venous reflux is still limited and attempts to overcome reflux with interventional techniques still have a low success rate. Moreover, surgical treatment, which seems to be the only option in patients with post-thrombotic etiology, is still controversial [27]. The lack of treatment options forces researchers to develop new techniques [28-31]. A relatively high success rate was achieved in early and mid-term follow up results of our cohort in our study; however, the late results should also be evaluated.

Limitations

Although we report a single-center prospective experience on a novel method, there are many drawbacks in this study. The follow-up times provide only early- and mid-term results with limited information on symptoms. We cannot comment on the effects of parallel development of additional reflux sites, which could be regarded as a late failure of the procedure. Moreover, hospital stay costs involved with returning to work, and overall treatment costs are not calculated. Another limitation may be regarded to the relatively small cohort size. Additionally, the technique requires expertise and good quality duplex US devices. The duplex US quality significantly reduces after polymerization of the hyaluronic acid and n-BCA combination when interacts with the tissue; hence, the approximation of the valves should clearly be visualized and degree of the reflux should not be relied on the red-blue color changes.

Conclusion

In conclusion, the internal compression therapy with the novel ICT (Internal Compression Therapy) Paravalvular Leak Device (Invamed, Ankara, Turkey) seemed safe, effective, and feasible in treating PDVI. The deep vein caliber reduces with the administration of hard gel over the vein wall to form an exoskeleton and prevents valvular leakage. The initial findings are promising; however, comparative randomized clinical trials are warranted to evaluate the long-term results and improve the quality of the system.

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Conflicts of interest

None

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