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Denali Inferior Vena Cava Filter Retrieval: Complications and Success Rates

Denali 하대정맥 필터 제거: 합병증과 성공률

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Purpose The present study was to evaluate the outcomes of Denali filter retrieval.

Materials and Methods We retrospectively reviewed 143 patients who received Denali filter insertion from September 2015 to April 2020. Ninety-seven patients who required removal of the filters were include in this study. Filters were retrieved with either standard or advanced techniques. Venography before and after retrieval was obtained to evaluate technical success, complications and duration of filter insertion.

Results All 97 filters were retrieved successfully without complications. Ninety-two (94.8%) were retrieved with standard technique and 5 filters (5.2%) required the advanced technique. There were two cases with a filter angle greater than 15 degrees. Inferior vena cava penetration was shown in 17 patients (17.5%) on venography but was not associated with contrast media extravasation after filter removal.

Conclusion The Denali filter showed a high rate of successful retrieval without complications. This study adds value to previous studies and trials showing that the Denali filter is a reliable and safe filter that can potentially improve retrieval rates, with increasing use of this device.

Index terms Vena Cava Filters; Pulmonary Embolism; Venous Thrombosis

INTRODUCTION

Preventing pulmonary thromboembolism (PE) in deep vein thrombosis (DVT) patients is crucial to reduce patient morbidity and mortality. Numerous risk factors contribute to throm-

boembolism, and some cases require prophylactic interventions, thus increasing the risk for thromboembolism if left untreated (1, 2). Pharmacologic therapy has been the first line of treatment for preventing PE. However, patients may not be eligible for this treatment if they are at high risk of bleeding tendency or experience recurrent episodes of thromboembolism (3). Mechanical thromboprophylaxis, which has been widely available since late 1960s (4), can be considered as an alternative in such instances. Although placement of a mechanical inferior vena cava (IVC) filter is generally considered safe, there are several perioperative and delayed complications associated with the use of these filters. Perioperative complications include access site bleeding, infection, filter tilt, and incomplete opening. Delayed complications include filter migration, fracture, thrombosis, pulmonary embolism, vessel injury and device embolization (3). To address these issues, retrievable filters have been developed.

The Denali vena cava filter is one of the newest generations of retrieval filters available for use in the United States (5). Several studies have compared the clinical outcome of classical IVC filters and the Denali filter. However, few studies have focused on retrieval of the filter with a relatively large sample size. In addition, few studies have evaluated the effects of filter deployment duration on filter retrieval (5-11).

The present study was designed to evaluate the outcomes of Denali filter retrieval after treatment in patients with DVT with respect to the rate of technical success, complications, and duration of filter insertion.

MATERIALS AND METHODS

The Institutional Review Board approval was obtained before the study initiation (IRB No. 2021-04-057-001). The IRB waived the requirement to obtain an informed consent from the patients for this retrospective data review.

POPULATION

This retrospective study was conducted in a single institution from September 2015 to April 2020. A total of 143 patients were underwent Denali vena cava filter placement during the period. Patients with evidence of DVT with PE (n = 51) or without PE (n = 92) with a clinical indication for IVC filter placement because of contraindication to or failure of anticoagulation were included. Among the 143 patients, 46 patients were excluded who still required the filter to prevent PE (n = 19) or were lost in follow-up (n = 11) or death (n = 16). A final group of 97 patients no longer required mechanical protection against PE as a DVT treatment. Filter retrieval was attempted for them and they were enrolled in this study.

Clinical and imaging data was collected from the electronic medical record (EMR)-centered integrated medical information system (CUBIS) and Infinitt PACS M6.

FILTER PLACEMENT AND RETRIEVAL

Of the 97 patients, 95 patients underwent lower extremity vessel spiral CT with enhancement at our institution while others had lower extremity Doppler ultrasonography or outside CT imaging to evaluate DVT.

The Denali vena cava filter (Bard Peripheral Vascular, Tempe, AZ, USA) deployment was

planned using the pre-procedural image. Two radiologists (Y.M.H with 30 years of experience and K.Y.K with 6 years of experience) were randomly assigned for the procedure. Filters were placed with the delivery system in either jugular or femoral access. Placement was performed according to Society of Interventional Radiology (SIR) guidelines (2). The delivery system contained 0.35-inch guidewire, 8- and 10-Fr dilators, an introducer sheath, a pusher, and the filter. The right femoral vein was the first choice for access site at our institution and also selected according to the preference of the interventional radiologists (12).

When retrieval was needed, the standard loop snare technique was initially attempted with the Bard Snare Retrieval Kit as recommended by the manufacturer (5). Using an 11F access sheath and a 9F retrieval sheath, the hook was snared and the 9F sheath was advanced to partially collapse the filter. Then the 11F sheath enclosed filter arms, allowing the filter and 9F sheath to be removed (5). Retrieval was attempted through the right jugular vein. If the standard technique failed, we used the loop and snare method through the filter apex, and this was considered as advanced retrieval (13). Right femoral vein was punctured in addition, a balloon was inflated between the filter and caval wall and realign the filter by reducing the tilting angle. Radiologists were randomly assigned to retrieve the filter, despite who initially placed the filter. After retrieval IVC filter, we performed IVC cavography which was checked for IVC complication such as perforation.

Procedure time was measured from the time initial venography to the time suture of puncture site, referring to the EMR record.

IMAGE ANALYSIS

Venography was obtained before and after filter deployment as well as before and after retrieval. Three radiologists participated in data collection. One radiology resident and one junior interventional radiologist (4 years of experience) independently measured the filter tilting angle. The principal investigator of this study reviewed measurement images from both radiologists, and then chose a more appropriate measurement.

Complications associated with filter deployment and retrieval, such as IVC penetration, filter tilt, filter migration and fracture, were evaluated by two interventional radiologists who performed the procedure.

IVC penetration was examined on venography and evaluated according to the Quality Improvement Guidelines for the performance of IVC Filter Placement revised by the American College of Radiology (ACR) in collaboration with SIR (14). IVC penetration was defined as penetration of the vein wall by a filter strut or anchor device extending more than 3 mm outside the IVC wall on CT or venography (3).

Filter tilt is one of the insertion problems and was defined by more than 15 degrees from the long axis of the IVC at the level of the filter hook. Filter tilt was examined on the coronal image of venography (3).

Filter migration can occur in cases of a filter fracture and was defined as more than 2 cm displacement of the IVC filter from its original position (3). Filter fracture was defined as the loss of structural integrity leading to fragmentation and embolization (3). The two radiologists assessed whether filter retrieval was successful, and successful retrieval was defined as complete removal of filter without remaining filter fragments (15).

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STATISTICAL ANALYSIS

Filter migration, fracture and IVC penetration were evaluated as either presence or absence. The time required for the procedure and the filter angle were evaluated as continuous values. Differences in filter insertion time and retrieval time between the two radiologists, and between standard and advanced technique groups were compared using Mann-Whitney U test. Tilting of the filter at the time of filter insertion (pre angle) and at the time of retrieval (post angle) was compared using Wilcoxon signed-rank test. A p value less than 0.05 was considered to indicate statistical significance. Values were expressed as mean ± standard deviation. Statistical analysis was performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 97 patients underwent retrieval of a Denali IVC filter from September 2015 to April 2020. The patient group included 33 male and 64 female, with an age range from 27 to 90 years (mean 68.3 years). Eighty-one patients were diagnosed with left side DVT, while 16 patients with right side. In 81 patients (83.5%), filters were inserted through right femoral vein; filters were inserted through left femoral vein in 5 patients (5.2%) and through right internal jugular vein in 11 patients (11.3%). Among the 97 patients, 61 (62.9%) had the filter for less than 30 days, and 36 (37. 1%) had the filter for more than 30 days (Table 1).

All 97 filters were successfully retrieved through right internal jugular vein. In 92 patients (94.8%), filters were removed by standard technique while 5 (5.2%) filters required advanced retrieval technique of balloon dilation assistance via the right femoral vein due to filter tilting. Two out of the five (40%) advanced technique patients had the filter for less than 30 days, and three (60%) had the filter for more than 30 days. All filters were successfully retrieved through right internal jugular vein (Fig. 1). There were no significant differences in patient characteristics between standard technique and advanced technique. Filter retrieval time was significantly higher in advanced technique group (15.4 and 35.2 minutes, respectively; $p = 0.001$) (Table 2).

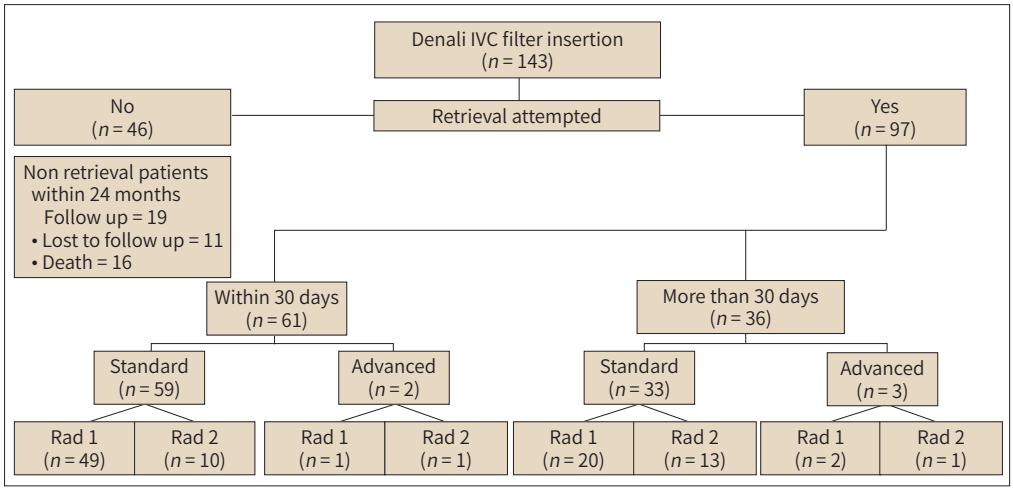
Filter insertion time did not show statistically significant differences between the two radiologists, but the radiologist with more experience took less time for filter retrieval ($p = 0.004$) even with advanced retrieval techniques of 4 cases (75%) as compared with 1 case (25%) in

Table 1. Characteristic of the Patients ($n = 97$)

Characteristics	
Age (years)	68.3 ± 16.0 (range, 27–90)
Sex, male:female	33:64
IVC diameter (mm)	20.5 ± 3.45
Filter indwelling time (days)	39.8 ± 60.8 (range, 3–565)
Access route	
Insertion through right femoral vein	81 (83.5)
Insertion through left femoral vein	5 (5.2)
Insertion through right internal jugular vein	11 (11.3)
Retrieval through right jugular vein	97 (100)

Data are mean ± standard deviation or n (%) values.

Fig. 1. Breakdown of IVC filter placement and retrieval during the study.



IVC = inferior vena cava, Rad = radiologist

Table 2. Comparison between Standard Retrieval Technique and Advanced Retrieval Technique

	Standard Technique (*n* = 92)	Advanced Technique (*n* = 5)	*p*-Value
Age	68.7 (range, 21–90)	61.4 (range, 31–78)	0.356
Sex, male:female	32:60	1:4	0.659
IV diameter (mm)	20.4 ± 3.43	22.4 ± 3.74	0.184
Access route			
Right femoral vein	78	4	
Left femoral vein	5	0	
Right internal jugular vein	9	1	
Insertion time (min)	10.9 (range, 4–25)	11.0 (range, 5–24)	0.532
Retrieval time (min)	15.4 (range, 6–37)	35.2 (range, 21–50)	0.001*
Pre angle (°)	4.3 (range, 0.5–15.8)	8.1 (range, 2.3–17.2)	0.110
Post angle (°)	4.9 (range, 0.6–16.0)	5.9 (range, 1–16.4)	0.660

*Statistically significant difference between standard and advanced technique ($p < 0.005$).

Table 3. Comparison of Filter Insertion Time and Retrieval Time between the Two Interventional Radiologists

	Radiologist 1	Radiologist 2	*p*-Value
Filter insertion time (min)	10.72 ± 4.45	9.21 ± 2.75	0.225
Filter retrieval time (min)	15.75 ± 6.54	22.35 ± 12.05	0.004*

*Statistically significant difference between radiologist 1 and 2 ($p < 0.005$).

less experienced radiologist (Table 3).

The mean indwelling time was 39.8 ± 60.8 days (range, 3–565 days). A total of 62.9% of filters were retrieved after indwelling times longer than 30 days (Table 1, Fig. 2).

Two (2.4%) filters showed a filter tilt with an angle greater than 15 degrees, but they were successfully retrieved without any complications. The filter angle ranged from 0.5 to 17.2; the mean angle after filter deployment was 4.51 ± 3.19 degrees and 4.92 ± 3.31 degrees just before retrieval (Fig. 3, Table 4). Patients with the greatest filter angle showed 16.5 degrees after

Fig. 2. Filter indwelling time (the duration in days between the initial implantation procedure and filter retrieval) for the 97 successfully retrieval filters. The mean indwelling time is 39.8 ± 60.8 days (range, 3–565). A total of 62.9% of filters are retrieved after 30 days.

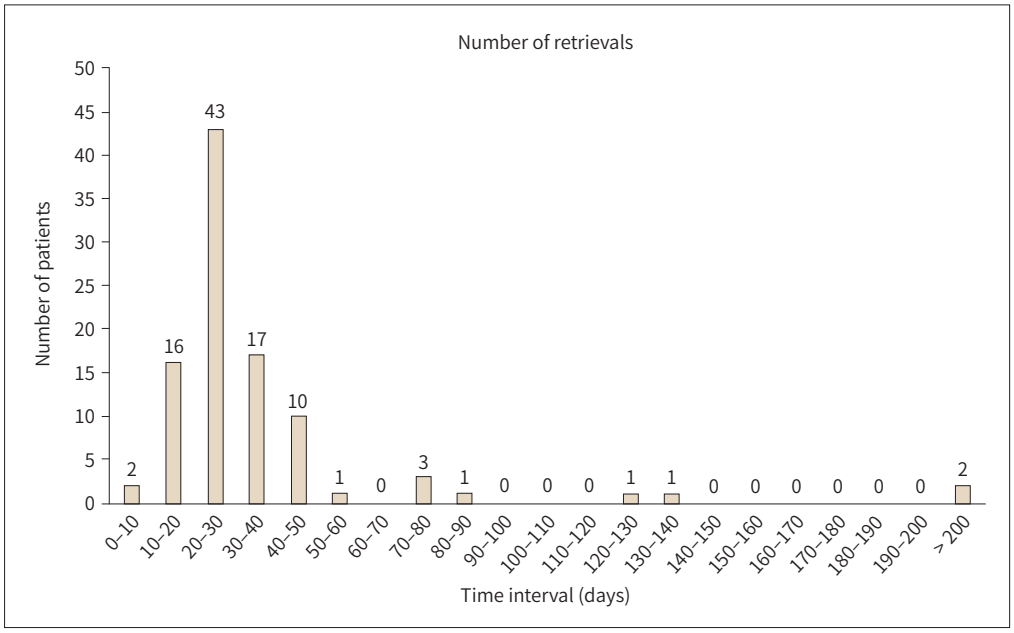
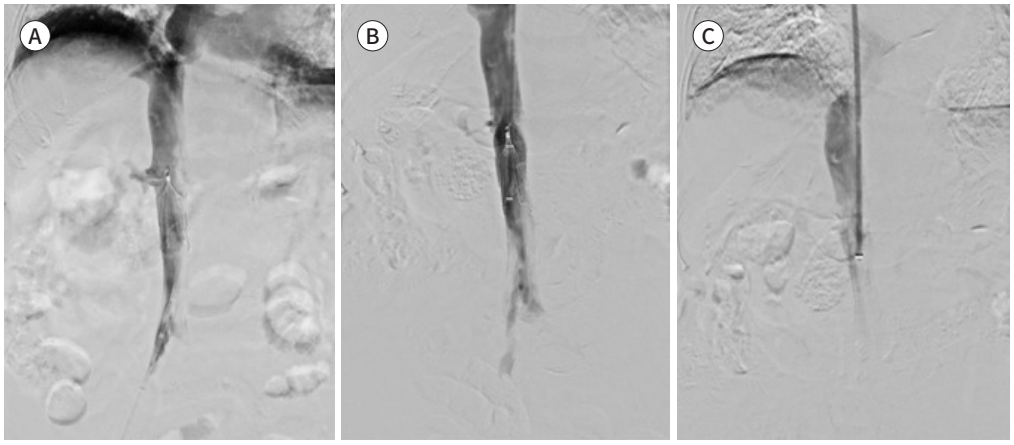


Fig. 3. Inferior vena cavographies of a patient show a tilting angle of 1.3° and 0.8° after implantation and before retrieval.
A. After filter implantation.
B. Before filter retrieval.
C. After successful filter retrieval.



deployment and 16.4 degrees before retrieval (Fig. 4) and did not show any complication during the retrieval. IVC penetration was shown in 20 patient (20.6%), but all of cases were not associated with contrast media extravasation after filter removal or the failure of removal.

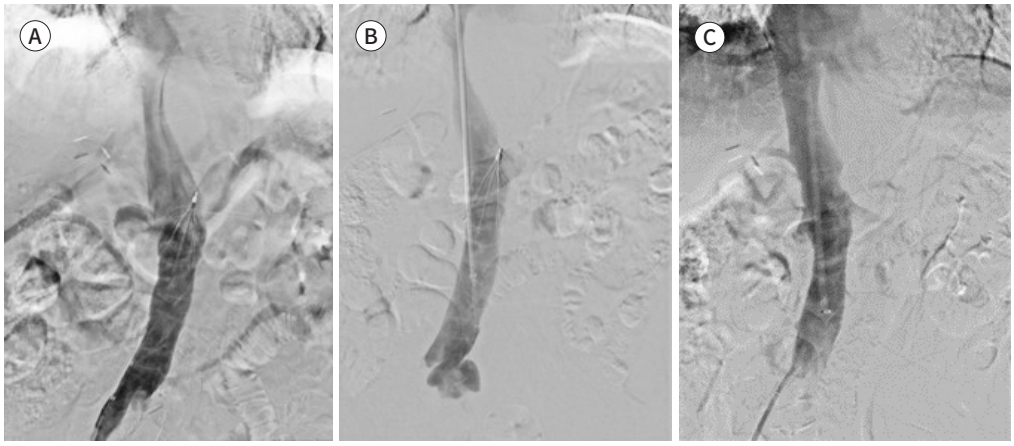
There was no difference in the filter tilt after implantation (p = 0.565) and before retrieval (p = 0.341) between the two groups according to length of time of filter indwelling (less than [p = 0.588] or greater than 30 days [p = 0.258]) (Table 4). Patient who had the filter for more than 30 days had the filter for a mean of 565 days but showed no filter tilt before retrieval, and the filter was successfully retrieved. In both groups, no filter migration, fracture, vessel perfo-

Table 4. Tilting of the Filter at the Time of Filter Implantation (Pre Angle) and before the Retrieval (Post Angle)

	Pre Angle (°)	Post Angle (°)	*p*-Value
All patients (*n* = 97)	4.51 ± 3.19	4.92 ± 3.31	0.270
≤ 30 days (*n* = 61)	4.56 ± 3.53	4.75 ± 3.42	0.588
> 30 days (*n* = 36)	4.42 ± 2.56	5.22 ± 3.15	0.258
p-value	0.565*	0.341†	

*No statistically significant difference was found between the pre angle of ≤ 30 days and > 30 days group.
†No statistically significant difference was found between the post angle of ≤ 30 days and > 30 days group.

Fig. 4. Inferior vena cavographies of a patient show a tilting angle of 16.5° after implantation and 16.4° before retrieval.
A. After filter implantation.
B. Before filter retrieval.
C. After successful filter retrieval.



ration, or device embolization was observed.

DISCUSSION

The technical success rate of Denali vena cava filter was 100% regardless of filter tilting and indwelling time in this study. The Denali filters can be retrieved without filter fracture, migration or IVC penetration during the period of up to 565 days of indwelling time. One of the common causes of filter retrieval failure is the long indwelling period. The DENALI trial reported a mean indwelling time of 165 days and the longest period of 632 days (10). Even though the mean indwelling time of IVC filters in this study was 39.8 days, the maximum indwelling time of 565 days is comparative to that of DENALI trial (10). Consequently, our results proved that successful retrieval was not dependent on the indwelling time and can be retrieved with adequate technique when the retrieval is required.

Ramaswamy et al. (7) reported that the Denali filter has fewer device-related complications than other retrieval filters, such as the Option or Tulip filters. However, there is still a concern regarding fracture of Denali filter. Kuo and Robertson (16) reported a case of a fractured Denali leg that was embolized to the heart, resulting in pericardial tamponade. Sathyanarayana et al. (17) also reported that the arm separated from the superior hinge was successfully

removed by snare. These reports imply a potential vulnerability of Denali filter at the hinge points in the arms. In our study, there was no filter fracture.

Filter strut and tip penetration in the IVC wall is another common cause for retrieval failure (6), but the mechanism is not well established. Jia et al. (18) suggested that conically shaped filters with free strut, which includes the Denali filter, have a higher association with caval penetration compared with the filters without free struts. The DENALI trial reported a caval penetration rate of 1.6% in 2016 (6) and Hightower et al. (19) reported the rate of 13% in 2018 (18). However, in our study, IVC penetration showed 17 patient (17.5%) in IVC venography before retrieval filter. Most of the penetration was measured between 3 to 4mm, which was around the cut-off value of 3 mm, and could be regarded to be a minor penetration. As a result, despite the presence of penetration, filters could be removed without complication.

Our study has several limitations. First, a limited number of retrievals was included compared with the DENALI trial (10), in which 124 retrievals were attempted. Second, the retrospective design of this study limited the population to patients who voluntarily underwent regular outpatient visits. Whether all patients requiring filter retrieval during the study period were included in this study is unclear, as we might have lost some patients who missed their regular visits. Third, the two radiologists with different levels of experience and the nonstandard technique for the procedure may have influenced the retrieval complication rates. Thus, we evaluated the complication rates for each radiologist separately. Fourth, for the image analysis, we used two-dimensional image of venography. This could have excluded three-dimensional tilting, such as tilting in the anterior to posterior angle. Finally, we defined successful retrieval using technical aspects and did not include clinical outcomes that can cause patient symptoms, such as the rates of PE developing in patients with IVC filters.

In conclusion, the Denali filter showed a high rate of success in terms of safe placement and retrieval without complications. The present study adds value to the previous studies and trials, proving that the Denali filter is a reliable and safe filter with prolonged indwelling time. Therefore, use of the Denali filter can potentially improve retrieval rates as the clinical use of this device prevails.

Author Contributions

Conceptualization, H.Y.M., K.K.Y., H.H.P.; data curation, all authors; formal analysis, all authors; investigation, H.Y.M., K.K.Y.; methodology, all authors; project administration, H.Y.M.; resources, H.Y.M., K.K.Y., H.H.P.; software, H.Y.M.; supervision, H.Y.M., H.H.P.; validation, H.Y.M., K.K.Y.; visualization, H.Y.M., K.K.Y.; writing—original draft, C.S.; and writing—review & editing, H.Y.M., C.S., H.H.P.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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Denali 하대정맥 필터 제거: 합병증과 성공률

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목적 본 연구는 Denali 필터 제거의 결과를 평가하기 위해 설계되었다.

대상과 방법 2015년 9월부터 2020년 4월까지 Denali 필터 삽입을 받은 143명의 환자를 후향적으로 분석하였다. 이 중 필터 제거를 필요로 하는 97명의 환자가 연구에 포함되었다. 표준방법 또는 심화기술로 필터를 제거하였다. 제거 전후로 정맥조영술을 얻어 성공적인 제거율과 합병증 여부, 필터 삽입에 걸린 시간에 대해 분석하였다.

결과 97명의 환자들이 모두 합병증 없이 필터를 제거하였다. 92명(94.8%)에서는 표준방법으로 제거했고 5명(5.2%)은 심화기술로 제거하였다. 필터 각도가 15도 이상인 예가 2건 있었다. 정맥조영술(venography)로 필터가 하대정맥에 박힌 사례가 17건(17.5%)이 있음을 확인했으나 필터 제거 후 조영제 유출과는 관련이 없었다.

결론 Denali 필터는 합병증 없는 높은 성공적 제거율을 보였다. 본 연구는 기존 연구 및 실험과 같이 사용이 증가하는 Denili 필터는 높은 제거율을 보여주는 신뢰할만하고 안전한 필터임을 보여주었다.

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