

"Of the 52 operated patients, there were 4 relapses (7.7 %) in classic CHIVA cases and 0% in CHIVA with EVLC and sclerotherapy cases.

Hemodynamic surgery of varicose veins of the lower extremities with the introduction of modern technologies

1- Short followup." The patients were thoroughly re-examined six months and a year after the intervention".
2- CHIVA with EVLC and sclerotherapy. The relapses (Shunt 3) to 10 mm of diameter, thus it can be behind proper potential venous graft.

3- Of 52 cases of relapses "a-1 relapse type 1" of the saphenofemoral junction: the technique of surgery of the saphenofemoral junction is not described although it is decisive in avoiding recanalization.

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2 cases of type relapses AS shunts types I to 6 not specified, the 2 cases of 4 relapses (restoration of reflux from the great saphenous vein to the tributaries of the second and third orders) may be due to Shunt 3 not properly treated or stump left behind.

c-1 "Relapse 3". Restoration of reflux due to failed femoral perforating veins that were not detected during the initial procedure. The "not detected" could have been cause of relapse also in CHIVA with EVLC and sclerotherapy group.

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Minimally invasive and pathogenetically based methods are currently prevalent in phlebology, as they are in other fields of surgery. CHIVA (Cure conservatrice et hemodynamique de l'insuffisance veineuse en ambulatoire) hemodynamic surgery is one of these popular minimally invasive surgical procedures. The execution technique relies on the findings of a duplex ultrasound scan that is used to analyse the hemodynamics of the superficial venous network. The CHIVA strategy aims to preserve the venous material while also restoring normal distal venous pressure and venous function. However, this technique has a number of disadvantages, including the possibility of vein recanalisation and relapses, as well as the fact that the immediate cosmetic outcome is not always satisfactory.

OBJECTIVE — to compare the outcomes of lower extremity varicose vein treatment based on the employed method: the CHIVA method executed via open surgery versus the CHIVA method combined with other minimally invasive methods (sclerotherapy, endovenous laser coagulation (EVLC)).

MATERIALS AND METHODS. A randomised prospective study was conducted on 52 patients with varicose veins of the lower extremities categorised as C1-C3 according to the CEAR classification. The patients were divided into 2 groups of 26 patients each, with one group undergoing the CHIVA procedure using the classic open technique, and the other group receiving a combination of CHIVA with EVLC and sclerotherapy. To evaluate the results, we used Hobb's criteria, measured the diameter of the great saphenous vein via ultrasound, analysed alterations in the Venous Clinical Severity Scoring (VCSS), studied data from the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ 20), and determined the incidence of relapses.

RESULTS. After CHIVA and CHIVA+EVLC+ sclerotherapy, the normalisation of hemodynamics and interruption of the venous shunt led to a substantial reduction in the diameter of the great saphenous vein within 6 months after the operation ($p < 0.01$). Both groups had an improvement in VCSS 6 months after surgery. No statistical difference was observed between the treatment groups. All methods had a positive impact on the quality of life of patients, as shown by the CIVIQ 20 questionnaire. Of the 52 operated patients, there were 4 relapses (7.7%). No relapses were noted in the group receiving CHIVA with EVLC and sclerotherapy ($p = 0.039$). As evaluated by Hobb's criteria, patients exhibited greater satisfaction with the outcomes of hemodynamic surgery combined with EVLC and sclerotherapy due to its better and faster aesthetic outcomes ($p = 0.012$ and 0.05).

CONCLUSIONS. All 52 patients exhibited favourable treatment outcomes, demonstrating a reduction in CVI symptoms during a comprehensive clinical assessment using ultrasound within 6 months and 1 year. The combination of CHIVA with EVLC and sclerotherapy showed distinct advantages in the treatment of varicose veins, yielding the most favourable cosmetic outcomes according to Hobb's criteria and achieving a recurrence rate of 0%.

KEYWORDS

chronic venous insufficiency, varicose veins, CHIVA, hemodynamic surgery, endovenous laser coagulation, sclerotherapy.

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Varicose veins in the lower extremities are a common manifestation of chronic venous insufficiency (CVI). The worldwide prevalence of varicose veins ranges from 5 % to 15 % among men and from 3 % to

29 % among women, depending on the age, sex, and ethnicity of the study population, survey methods, and how the disease is defined and measured [11, 20]. The spectrum of clinical manifestations of CVI

is huge, ranging from asymptomatic varicose veins and pigmentation to ulcers and scars. To identify, diagnose and treat CVI, it is necessary to understand the full spectrum of clinical manifestations, etiology and pathogenesis of the disease, as well as diagnostic methods [20]. Among diagnostic methods, the universally accepted gold standard is ultrasound with Doppler mapping [3, 6].

Minimally invasive techniques are prevalent not only in phlebology but in all areas of surgery. Currently, the method proposed by C. Franceschi in 1988 can claim the role of a less traumatic approach [5, 6]. The literature refers to the ambulatory conservative treatment of hemodynamic venous disorders (Cure conservatrice et hémodynamique de l'insuffisance veineuse en ambulatoire) as CHIVA. Unlike other operative methods of treating varicose veins, which are performed in accordance with an established protocol, the hemodynamic approach involves assessing individual venous hemodynamic characteristics using an ultrasound Doppler scan [3, 5]. Due to the complexity of such a personalised assessment, this technique is not very popular in our country. According to the literature, it is most often used in Italy and Spain, but recent publications show that this method is now being actively used in other countries throughout the world [2, 15, 21].

The CHIVA method is based on the concept of venous shunts, which are veins that divert venous blood from its normal flow, most often during muscle relaxation. The significance of the shunt is determined by the deflected flow, the starting point and the end point of the deflection [5]. The starting point is called the escape point and/or reflux point, while the endpoint is called the re-entry point (usually the re-entry perforator). There are several classifications of shunts. The most common is a type 1 shunt, which has an insufficient saphenofemoral junction as an escape point and a re-entrant perforator on the trunk of the great saphenous vein as the endpoint [10, 16].

The CHIVA strategy is conservative not only because it preserves venous material, which may be required for further arterial shunting, but also because it prevents the hemodynamic disorders associated with subcutaneous vein destruction [14]. Violation of the normal outflow of venous blood through superficial veins causes tissue damage, recurrence of varicose veins as a result of induced neoangiogenesis, and the formation of reticular varicose veins and telangiectasias in the areas of vein removal. This approach is hemodynamic because it restores normal distal venous pressure and venous function [2, 10]. Values are assigned to the adequate outflow of venous blood into the deep network. For this reason,

limited venous interruptions are better than extensive ones, even if the immediate aesthetic outcomes are less satisfactory [19]. In fact, aesthetic outcomes improve over time, long-term outcomes are significantly better, and recurrences are far less common with fewer surgical interventions. However, any removal or occlusion of non-draining or redundant veins is not inconsistent with the CHIVA strategy [4, 13, 18].

Fragmentation of the venous pressure column and disconnection of venovenous shunts are usually performed by open surgery, but sclerotherapy (ST), endovenous laser coagulation (EVLC), or radiofrequency ablation may also be used. Only a few studies have compared the CHIVA method to other surgical approaches, mainly stripping [17]. Furthermore, there is insufficient research on the use of CHIVA principles in combination with other minimally invasive interventions and hardware techniques for varicose vein treatment [8, 12].

OBJECTIVE – to compare the outcomes of lower extremity varicose vein treatment based on the employed method: the CHIVA method executed via open surgery versus the CHIVA method combined with other minimally invasive methods (sclerotherapy, endovenous laser coagulation (EVLC)).

Materials and methods

A prospective randomised controlled study included 52 patients. The majority of these patients were women – 38 (73.1%).

The inclusion criteria:

- 1) the presence of varicose veins (C1-C3 class of varicose veins according to the CEAP classification);
- 2) age range: 18 to 65 years;
- 3) failure of the sapheno-femoral junction;
- 4) without previous surgical treatment in history;
- 5) patients with a capable deep venous system;
- 6) the patient's consent to participate in the study.

Exclusion criteria:

- 1) varicose vein complications (trophic ulcers, thrombophlebitis or phlebothrombosis, post-thrombotic syndrome);
- 2) patients who previously underwent radical operations for varicose veins;
- 3) patients with severe concomitant pathology that may affect treatment course and outcome (diabetes, autoimmune diseases, oncological diseases, severe kidney, liver, heart system, and lung diseases);
- 4) patient refusal, lack of compliance regarding the use of compression therapy and its duration.

In addition to general clinical examinations, all patients underwent a duplex ultrasound scan (USDS) of the veins of the lower extremities in

the supine and standing positions, using the Paran and Valsalva tests, with detailed mapping of the hemodynamics of the lower extremities [3]. When conducting a detailed ultrasound, insufficiency of the saphenous-femoral junction and the re-entrant perforator on the trunk of the great saphenous vein was revealed in all patients. According to CHIVA terminology, patients had a type 1 shunt.

The study was conducted in accordance with the principles of the Declaration of Helsinki and the recommendations of the International Council for the Harmonisation of Good Clinical Practice.

The treatment method was chosen by randomising all patients into two groups of 26 patients each. The first group of patients was treated according to CHIVA's standard principles. These patients underwent an incision 3 cm below the inguinal fold and ligation of the sapheno-femoral junction, which served as the so-called «escape point». Drainage flow took place in the re-entry perforator on the great saphenous vein. Miniphlebectomy was used to remove varicose veins and nodes with no obvious anastomosis of discharge.

The second group included 26 patients whose hemodynamic picture was comparable to the first group. The CHIVA technique was used in combination with EVLC and sclerotherapy. This method involved an incision of up to 1.5 cm long at the saphenous-femoral junction, coagulation using EVLC of the proximal 7–10 cm of the great saphenous vein below the junction, and the injections of a foam sclerosant (1% Ethoxysclerol) into venous branches of the 3–4 order, which lacked drainage anastomosis. These techniques were used to prevent recanalisation of the large subcutaneous vein in the proximal part, which is the most frequent cause of relapses after CHIVA with this type of shunt, and to ensure reliable closure of the tributaries of the great saphenous vein in the proximal part, thereby increasing the cosmetic outcome of the intervention by minimising the number of incisions necessary for miniphlebectomy.

All interventions were performed under local anesthesia with standard Klein's solution. In the case of combination with EVLC, Klein's solution was injected perivenously under ultrasound control [7]. In the post-procedural period, all patients received compression therapy, which included wearing medical compression stockings around the clock for the first three days, followed by daytime compression for the next three weeks.

The patients were thoroughly re-examined six months and a year after the intervention.

Relapse was considered the main endpoint of the study. During repeated visits, all patients underwent

USDS of their lower extremity veins with detailed hemodynamic mapping. A recurrence was defined as the visible appearance of varicose veins in the intervention area, the restoration of reflux at the previously detected site, changes in the direction of blood flow through the saphenous-femoral junction, perforating veins or tributaries of the great saphenous vein. All relapses were divided into 5 hemodynamic types:

Relapse type 1 – relapse with resumption of reflux through the sapheno-femoral junction.

Relapse type 2 – restoration of reflux through the venous path that leaves the pelvis through veins located in the groin or perineum without restoration of the sapheno-femoral junction.

Relapse type 3 – restoration of reflux due to failed femoral perforating veins that were not detected during the initial procedure.

Relapse type 4 – restoration of reflux from the great saphenous vein to the tributaries of the second and third orders. This is the most typical type of relapse for the CHIVA method.

Relapse type 5 – varicose veins to a diameter of more than 5 mm in the area of intervention without «escape points», which can be detected by Doppler examination. This is a typical relapse with stripping and other interventions aimed at destroying the great saphenous vein and is atypical for CHIVA.

For objectification, the cross-sectional diameter of the great saphenous vein in the middle third of the thigh, approximately 20–25 cm from the saphenous-femoral junction, was determined in all patients during repeated USDS.

A score was calculated using Venous Clinical Severity Scoring (VCSS) (in accordance with the Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum) [9].

Clinical evaluation of treatment outcomes after CHIVA and CHIVA modified methods was also carried out using Hobb's criteria, which were proposed by the authors of the method [5].

Hobb's criteria for evaluating the clinical outcome:

Objective criteria (assessed by a doctor)

Class A: no visible or palpable veins.

Class B: several visible or palpable veins less than 5 mm in diameter.

Class C: left or newly formed varicose veins with a diameter of more than 5 mm.

Class D: insufficiency of the main trunk of the great saphenous vein or perforator.

Subjective criteria (defined by the patient)

Class A: no complaints.

Class B: slight functional or cosmetic defect, but satisfied with the outcome.

Class C: noticeable functional or cosmetic defect. Clinical evaluation of the outcomes as improvement, but dissatisfaction with the overall result.

Class D: complete absence of positive changes after treatment or worsening of the condition.

The treatment outcomes were classified into three groups:

- complete recovery (complete absence of varicose veins and symptoms of CVI);
- improvement (visible residual or newly formed varicose veins or nodes that have no or little clinical and hemodynamic significance);
- absence of positive changes (complete recurrence of varicose veins, recurrence of symptoms of CVI).

Satisfaction with treatment outcomes was also assessed using the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ 20). In order to compare the average scores, the absolute scores were converted to a GIS index [1].

Statistical analysis

Statistical analysis was performed using Statistica 10 and MedStat. Data distribution normality was checked using the Shapiro-Uilk criterion. A comparison of the data between the groups was performed using the Wilcoxon two-sample test. Multiple comparisons were performed using the Rank Kruskal-Wallis test and Dunn's test, Scheffe's method for multiple comparisons.

Results and discussion

Since hemodynamic interventions do not remove all varicose veins, the majority of research sources suggest that the CHIVA method produces superior long-term results than immediate ones. This impact is related to the time that is required for hemodynamic reconstruction of shunts. Therefore, the final outcomes were evaluated after half a year and a year of observation:

Recovery is the complete absence of varicose veins and CVI symptoms. Results after 6 months: CHIVA – 15 (57.7%), CHIVA + EVLC + ST – 18 (69.2%).

Results after a year: CHIVA – 17 (65.4%), CHIVA + EVLC + ST – 20 (76.9%).

Improvements are visible residual or newly formed varicose veins or nodes that have no or little clinical and hemodynamic significance. Results after 6 months: CHIVA – 10 (38.5%), CHIVA + EVLC + ST – 8 (30.8%). Results after a year: CHIVA – 8 (30.8%), CHIVA + EVLC + ST – 6 (23.1%).

Without clinical changes – complete recurrence of varicose veins, presence of CVI symptoms. Results after 6 months: CHIVA – 1 (3.8%), CHIVA + EVLC + ST – 0. Results after a year: CHIVA – 1 (3.8%), CHIVA + EVLC + ST – 0.

A statistically significant difference between the groups was not found after half a year ($p = 0.348$) and after a year of observation ($p = 0.329$). The data show that any hemodynamic technique – standard or supplemented with modern technologies – provides a favourable clinical outcome.

OBJECTIVE – data, including the diameter of the great saphenous vein in the middle third of the thigh, VCSS scale, and data obtained using CIVIQ 20 before treatment, 6 months and 1 year after surgery, are shown in Table 1.

Hemodynamic methods in classical execution, or supplemented by modern technologies, give a good clinical result. No statistically significant difference was found between the groups depending on the treatment method ($p > 0.05$). According to the data of the clinical assessment and the questionnaire, a statistically significant difference was found between the values before treatment and 6 months after treatment ($p < 0.01$). Normalisation of hemodynamics and interruption of the venous shunt leads to a significant decrease in the diameter of the great saphenous vein already 6 months after the operation ($p < 0.01$). There was no statistically significant difference in the indicators after 6 months and after a year.

Analysis of the data presented in Table 2 reveals that, based on the objective assessment, there was no statistically significant difference in clinical treatment outcomes between the CHIVA group and the

Table 1. Data of objective examination methods before and after treatment

Indicator	CHIVA			CHIVA + EVLC + ST		
	Before	After 6 months	After 1 year	Before	After 6 months	After 1 year
Diameter of the great saphenous vein, mm	7.3 ± 1.7	4.2 ± 0.9	3.9 ± 1.1	7.2 ± 1.9	4.1 ± 0.8	4.2 ± 1.3
VCSS, points	8.9 ± 2.4	1.3 ± 2.1*	1.5 ± 7.2*	8.5 ± 2.8	0.6 ± 0.9*	0.5 ± 1.2
CIVIQ 20 (GIS)	71.44 ± 8.67	97.6 ± 5.4	95.8 ± 8.7*	74.13 ± 8.75	98.8 ± 1.6*	99.3 ± 1.4

* $p < 0.01$ compared to data obtained before treatment.

Table 2. Evaluation of clinical outcomes according to Hobb's criteria

Class	After 6 months		After 1 year	
	CHIVA	CHIVA + EVLC + ST	CHIVA	CHIVA + EVLC + ST
Objective assessment				
A	14 (53.8%)	18 (69.2%)	16 (61.5%)	20 (76.9%)
B	8 (30.8%)	8 (30.8%)	5 (19.2%)	6 (23.1%)
C	2 (7.7%)	0	4 (6.2%)	0
D	1 (3.9%)	0	1 (6.2%)	0
Subjective assessment				
A	12 (46.2%)	18 (69.2%)	15 (68.8%)	20 (76.9%)
B	3 (11.5%)	8 (30.8%)	3 (11.5%)	6 (23.1%)
C	10 (38.4%)	0	7 (26.9%)	0
D	1 (3.8%)	0	1	0

CHIVA group supplemented with additional technologies after 6 months ($p = 0.147$) and after one year ($p = 0.131$), respectively. A statistically significant change was seen after 6 months ($p = 0.012$) and after a year ($p = 0.05$) based on the subjective assessment. Therefore, patients expressed more satisfaction with the outcomes of hemodynamic surgery supplemented with EVLC and sclerotherapy because it provided better and faster aesthetic outcomes.

There were 4 relapses (7.7%) among 52 operated patients, indicating a favourable outcome. No recurrence was seen in the group receiving CHIVA in combination with EVLC and ST ($p = 0.039$).

All relapses were classified into hemodynamic types. Relapses of type 2 and type 5 were not detected. There were 2 cases of type 4 relapses, one case of type 1 relapse with restoration of reflux through the sapheno-femoral junction, and one case of type 3 relapse.

Currently, there is a shift in the methodology of surgical intervention for varicose veins from radical techniques to minimal and justified procedures, supported by the principles of minimally invasive and outpatient surgery. The use of USDS, which allows for comprehensive mapping of varicose veins, facilitates the identification of the sources and prevalence of venous reflux, as well as hemodynamic correction options for each type of lesion [2, 4, 22]. Now in the arsenal of surgeons, there is a sufficient number of minimally invasive methods that can be used to achieve this goal. The combination of minimally invasive technologies with a hemodynamic

approach provides optimal cosmetic outcomes by reducing both the number and length of incisions. Varicose vein sclerotherapy, combined with CHIVA, improves immediate cosmetic outcomes. Ablation of the proximal part of the great saphenous vein effectively facilitates reliable closure of the confluence of many tributaries and prevents recanalisation, thereby significantly impacting the incidence of relapses [8].

Conclusions

Hemodynamic methods, including standard CHIVA or CHIVA supplemented with modern technologies such as EVLC and sclerotherapy, ensured favourable clinical outcomes. Clinical assessment and questionnaire data revealed a statistically significant difference between values before treatment and 6 months after treatment ($p < 0.01$). The normalisation of hemodynamics and interruption of the venous shunt led to a substantial reduction in the diameter of the great saphenous vein within 6 months after the operation ($p < 0.01$).

According to Hobb's criteria, no statistically significant difference was observed between the treatment groups on the objective assessment scale. However, a statistically significant difference was noted on the subjective assessment scale after 6 months ($p = 0.012$) and after a year ($p = 0.05$) due to the fact that the patients achieved better and faster aesthetic outcomes.

Hemodynamic procedures resulted in a low incidence of varicose vein relapses, with just 7.7% reported among all patients. Notably, no recurrences were observed in the group when CHIVA was combined with EVLC and sclerotherapy ($p = 0.039$).

The study found that no approach has a clear advantage over others. It is important to select the optimal technique for each patient based on their venous system's haemodynamics, technical and economic capabilities, and desire for a quick cosmetic outcome.

DECLARATION OF INTERESTS

The authors have no conflicts of interest to declare.

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ETHICS APPROVAL AND WRITTEN INFORMED CONSENT STATEMENTS

The assessment and usage of all clinical data was approved and permitted before the study by the ethics committee of

Bogomolets National Medical University. The study protocol conformed to the ethical guidelines of the «World Medical Association (WMA) Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects» adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 59th WMA General Assembly, Seoul, South Korea, October 2008. Written informed consent was obtained from all individual participants included in the study.

AUTHORS CONTRIBUTIONS

I. V. Kolosovych: work concept and design, critical review;
K. O. Korolova: work concept and design, data collection and analysis, statistical analysis, writing the manuscript.

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Гемодинамічна хірургія варикозного розширення вен нижніх кінцівок із застосуванням сучасних технологій

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Нині у флебології, як і в інших галузях хірургії, трендовими є малоінвазивні та патогенетично обґрунтовані методики. Гемодинамічна хірургія СНІВА є малоінвазивною хірургічною процедурою. Техніка виконання ґрунтується на результатах ретельного аналізу гемодинаміки поверхневої венозної мережі за допомогою дуплексного сканування. Стратегія СНІВА спрямована на збереження венозного матеріалу, а також на відновлення правильного дистального венозного тиску та правильної венозної функції. Проте ця методика має низку недоліків, зокрема ризику реканалізації вен та рецидивів, а також не завжди дає задовільний безпосередній косметичний результат.

Мета — порівняти результати лікування варикозної хвороби нижніх кінцівок залежно від використаного методу лікування: СНІВА за допомогою відкритої операції або СНІВА у комбінації з іншими малоінвазивними методиками (склеротерапія, ендовенозна лазерна коагуляція (ЕВЛК)).

Матеріали та методи. У дослідження було залучено 52 пацієнти з варикозною хворобою нижніх кінцівок, С1–С3 клас за СЕАР класифікацією. Пацієнтів розподілили на дві однакові за кількістю групи, в одній виконано СНІВА за класичною відкритою методикою, в іншій застосовано комбінацію СНІВА з ЕВЛК та склеротерапією. Для оцінки результатів використовували критерії Хобса, визначення діаметра великої підшкірної вени за допомогою ультразвукового дослідження, оцінку за шкалою Venous Clinical Severity Scoring (VCSS), дані опитувальника Chronic Venous Insufficiency quality of life Questionnaire (CIVIQ 20), кількість рецидивів.

Результати. Після СНІВА та СНІВА+ЕВЛК+склеротерапія нормалізація гемодинаміки та переривання венозного шунта сприяла суттєвому зменшенню діаметра великої підшкірної вени вже через 6 міс після операції ($p < 0,01$). В обох групах зареєстровано поліпшення оцінки за VCSS через 6 міс після операції. Статистично значущої різниці між групами не виявлено. Обидві стратегії позитивно впливали на якість життя пацієнтів за опитувальником CIVIQ 20. Зареєстровано лише 4 (7,7%) рецидиви (усі в групі СНІВА) ($p = 0,039$). Пацієнти були більше задоволені результатами гемодинамічної хірургії, доповненої ЕВЛК та склеротерапією, при оцінці за суб'єктивними критеріями Хобса, оскільки застосування такої стратегії дало кращий і швидший естетичний результат ($p = 0,012$ та $p = 0,05$).

Висновки. Хороший результат лікування зі зменшенням симптомів хронічної венозної недостатності при комплексній клінічній оцінці з використанням ультразвукового дуплексного сканування через 6 міс та 1 рік зареєстрували в усіх пацієнтів. Комбінація СНІВА з ЕВЛК та склеротерапією мала переваги: найбільша косметичність за суб'єктивними критеріями Хобса та відсутність рецидивів (0%).

Ключові слова: хронічна венозна недостатність, варикозне розширення вен, СНІВА, гемодинамічна хірургія, ендовенозна лазерна коагуляція, склеротерапія.

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