The place of mini-invasive Transanal-Hemorrhoidal-Dearterialisation and Rectopexy technique in the treatment of hemorrhoidal disease, an evaluation from cost-effectiveness point of view

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Background. Choosing the most suitable treatment for Hemorrhoidal Disease (HD) still poses problems for both patients and doctors. THD-RAR although it has proven its superiority regarding postoperative complications, length of hospital stay, return to daily activity compared to Hemorrhoidectomy (HE), it still has a low rate of less than 10% in our hospital, the main causative factor being the increased cost of consumables. Our aim is to analyze the veracity of this factor.

Methods. We performed a case-control study in the period 2009-2022 and we evaluated two groups of 50 patients, operated by the THD-RAR method and HE respectively. We had as Main Objective the comparison of average hospitalization costs and as Secondary Objectives the evaluation of postoperative hospitalization, complications, recurrences, the influence on the final cost of social costs.

Results. Financially, the elderly had less accessibility to THD-RAR. Internal hemorrhoids predominated in the THD-RAR-group and associated ones in the HE-group (64% and 48%, respectively; p<0.001). Bleeding was the predominant symptom in THD-RAR-group versus prolapse in the HE-group. The mean operation time was longer in THD-RAR compared to HE (48 and 56 min respectively; not significant). The significantly longer postoperative hospital stay in the HE-group compared to the THD-RAR-group (2.52 versus 1.74 days; p<0.001), obviously influenced the hospitalization expenses (834 versus 485 EUR; p<0,001). Thus, although the expenses with the operation were higher for THD-RAR compared to HE, in the end summing up the hospitalization expenses and the social expenses, the difference tilted in detriment of HE (277 EUR).

Conclusion. Our study shows that if we subtract from the amortization expenses, the savings made from hospitalization expenses and social expenses, then THD-RAR-HE balance will be in favor of THD. THD-RAR must take its place both in the hospitals' own therapeutic protocols and in the national guidelines, being a cost-effective method.

Keywords: THD-RAR, hemorrhoidectomy, mini-invasive, cost-effectiveness, implementation

BACKGROUND

Although not a life-threatening condition, Hemorrhoidal Disease (HD) is a socially important disorder, with a prevalence of 4.4%, over 50% of the population having at least one acute episode of HD during their lifetime and representing the most important percentage of consultations in proctology offices. Despite the

fact that there is a representative armamentarium of therapeutic procedures for this disease, the choice of the most suitable one still poses problems for both doctors and patients. The Transanal Hemorrhoidal Dearterialization and Rectoanal Repair technique (THD-RAR) is a relatively new procedure, developed especially in the last 20 years, it being a physiopathological and mini-invasive operation. This technique can be practiced in both inpatient and outpatient settings and has proven its superiority in terms of postoperative pain, postoperative complications, length of hospital stay, time of social reintegration compared to classic Hemorrhoidectomy (HE). However, it still has a low share among the surgical procedures for the treatment of HD, currently occupying a percentage slightly below 10% of the total number of interventions performed in our hospital for HD. We found that the main factor that led to the reduced implementation of the THD-RAR method was the increased cost of the device and consumables used for this operation. We aim of out to study is to analyze the veracity of this factor and what other elements contributed to this evolution.

MATERIALS AND METRODS

We conducted a case-control study in which we constituted and evaluated two groups of 50 patients each, the Study Group – operated by the THD-RAR method and the Control Group – operated by the HE method. The study was of mixed retrospective and prospective type, spread over a period of 13 years (2009-2022), the choice of cases being made according to the principle of each case operated by the THD-RAR method, the first case operated by the HE technique. The study was carried out in the Bucharest Emergency Clinical Hospital (BECH), the operations being performed by surgical teams specialized in the treatment of HD. Inclusion criteria were patients of any sex and age, operated by the THD-RAR or HE method, including certain minor associated conditions (Acute fissures, Anal or colonic polyps, Isolated external hemoroids, Sebaceous Cyst) admitted to BECH surgery department. Exclusion criteria were patients operated by other surgical methods (including endoscopic), with associated anorectal conditions that prolonged the length of hospitalization independent of HD (perianal suppurations, fistulas, chronic fissures), patients operated for hemorrhoidal recurrences, patients with complications like hemorrhoidal thrombophlebitis, patients with severe cases who required prolonged hospitalization for other reasons than the evolution of HD. We used the classic classification of hemorrhoids into internal, external and associated hemorrhoids, the internal ones being in turn classified according to the degree of prolapse into grade I (without prolapse), II (spontaneously reducible prolapse), III (manually reducible prolapse), IV (irreducible prolapse) according to Goligher. Most of the interventions were done under spinal anesthesia, general anesthesia being an exception that was applied only to patients who had contraindications for spinal anesthesia or expressly wanted it. The THD-RAR intervention was performed using the AMI-II system that uses an anoscope with a disposable Doppler probe and resterilizable handle. The technique applied was suturing the upper rectal arterial branches, after their identification with the Doppler probe (5-7 branches) followed by runnig suture in 5 steps of prolapsing mucosa with the same thread (3-6 sutures) adapted to the localization and degree of hemorrhoidal prolapse. The HE technique applied was the classic Milligan-Morgan technique, avoiding the inclusion in the study of cases where only two hemorrhoidal excisions or modern vascular sealing devices (Ligasure, Harmonic Scalpel) were used.

We had as the Main objective the comparison of the average hospitalization costs for the two groups and as Secondary objectives the evaluation of the number of postoperative hospitalization days, complications, relapses, the highlighting of the factors that influenced the days of hospitalization and the evaluation of the influence on the final social costs by the time of social reinsertion according to each method.

To evaluate the cost of materials, we used the acquisition values of the instruments and consumables valid for the year 2021. For the cost of hospitalization, we used the values from the statement of hospitalization expenses (according to national order 1100/14.10.2005, this being corrected according to the number of postoperative hospitalization days and updated to the increased values after 2018 for cases operated before this date). We calculated the Social Costs according to the number of days of sick leave recommended for each type of intervention carried out using the percentage from code 1 of the social insurance health insurance allowance (mean 75%) applied to the average salary in the economy at the level of 2021. The social costs due to reinterventions were also taken into account where they were necessary.

In order to be able to compare the data obtained with the data published in the literature, we studied the articles published using the Google search engine and the Medline, Cochrane and UpToDate medical databases using as search terms: THD, rectopexy, hemorrhoidectomy, cost-effectiveness, from which we selected significant articles for this topic.

For data collection and processing we used the Microsoft Access 2010 program and for the statistical calculation the Microsoft Excel and SPSS programs. For the quantitative variables we used the Student test and for the qualitative variables the Pearson chi-square test, taking the values below $\alpha = 0.05$ as the limit of statistical significance.

RESULTS

Analyzing the demographic parameters of the studied groups, it can be seen, from the results presented in Table 1, that the share of male patients (66.0%) is significantly higher than that of female patients (34,0%) (c2(df=1) = 10,24 and p < 0,001)).We can consider the prevalence of male gender for this type of disease. From the point of view of the distribution of gender categories in the two groups, it can be assumed that it does not differ according to group type (c2(df=1) = 0,71)si p < 0,05), which is why it can be assumed the fact that the two groups are random selections from the population of patients with this type of disease. Studying the distribution by age groups, by applying the Kolmogorov-Smirnov normality test the age distribution approximates a normal distribution of parameters m @ 50 years with a standard deviation sd @ 14 years. If we compare the ages between the two groups (see Table 2), a higher level of age (m = 53.48; sd = 15.14) is observed in the case of the control group compared to the level of the study group (m = 45.41; sd = 12.02), statistically significant difference for a comparison test value t (98) = 2.95 and p < 0.001. This can be explained by the possibilities and greater financial availability of younger people to invest in their own health (implicitly to opt for the THD-RAR technique that involves the patient paying for the supplies), all the more so as they are active people who are obviously bothered by HD symptoms.

The most common anatomical diagnosis (Figure 1) was internal hemorrhoids (64%), with a significantly higher weight (80%) in the case of patients in the study group compared to those in the control group (48%) for a $c^2 = 11,11$ and p < 0,001. In the case of patients in the control group, the share of the two types of hemor-

rhoids (internal and associated) is approximately equal. This is explained by the specific indication of hemorrhoids with a major external component for HE intervention. Regarding the classification according to the degree of prolapse (Figure 2), the highest proportion was observed in the case of stage 3 (57%), higher in the case of patients in the study group (62%). Stage 4 was present in 28% of patients in the control group, significantly higher than in patients in the study group for a value $c^2 = 8.94$ and p < 0.05. And here it is obvious that during a period of evaluation of the THD-RAR method, a more cautious approach through the classical HE technique was preferred for stage IV.

Among the complications (see Table 3) the most present is Rectoragia, with a weight of 76%, significant for a value of the Chi-square comparison test $c^2 = 27.04$ and p <0.001. Comparatively, patients in the study group presented to a significantly higher extent (66%) this complication for a test value $c^2 = 5.48$ and p <0.01. In the case of prolapse, patients in the study group presented this complication in a significantly lower proportion (42%) for a test value $c^2 = 11.42$ and p <0.01. In both groups, the associated secondary operations (excision of polyp, mariscum excision, anal dilatation) were significantly equal and fell into the type of minor operations that influenced to a small extent the operative time but also the hospitalization as a whole.

For both groups, the postoperative hospitalization varies between 1–6 days, with distributions showing a strong right-wing asymmetry, in the sense that the values lower than the mean value have a significantly greater weight than 50%, 54% in the case of the control group and 86% in the case of the study group, which is why the median value of the distribution will be considered as the average trend. The average level of hospitalization (Table 4) in the case of the Control Group (md

TABLE 1. Comparative analysis of the distribution of sex categories between the twogroups

			S	Sex		-2
Group type * Sex			male	female	Total	C-
Group type	Control group	Frequency	31	19	50	
		Percent (%)	62.0%	38.0%	100.0%	0.71
	Study group	Frequency	35	15	50	0.71
		Percent (%)	70.0%	30.0%	100.0%	
Total		Frequency	66	34	100	
		Percent (%)	66.0%	34.0%	100.0%	

Note: c^2 – the value of the Chi-square test comparing with an equi-probability distribution, ** - level of significance p < 0,001.

TABLE 2. Age distribution parameters by group type

	Group type	Ν	m	sd	Average difference	<i>t(df</i> =98)
Age	Control group	50	53.48	15.14	8.06	2.95**
	Study group	50	45.42	12.02		

Note: m – arithmetic mean, sd – standard deviation, t – t-test value comparing two independent samples, df – degree of freedom corrected according to Levene's test of homogeneity of variances



FIGURE 1. Diagnosis – Anatomical classification (Internal Hemorrhoids – Associated Internal and External Hemorrhoids)



FIGURE 2. Diagnosis - Classification by Stage (Goligher Stage 2-3-4)

@ 2.52 \pm 1.1) is higher than in the case of the Study Group (m @ 1.74 \pm 0.8), the trend difference is statistically significant for a standardized Mann-Whitney non-parametric comparison test value Z = 3.73 and p < 0.001.

In performing the hospitalization calculation, we made two corrections. The first is related to the days of hospitalization before the intervention, which we excluded from the calculation because they are not influenced by the type of intervention performed (this includes the investigations performed, the correction of anemia, the availability of the operating room). The second correction is related to the fact that after 2018 there was a major change in hospitalization expenses and food expenses compared to the period before

2018. Thus, the amount of these expenses increased from 308 RON/day to 1690 RON/day. For this reason, for a correct assessment of expenses, it was necessary to apply a Correction Coefficient of 5.5 for cases hospitalized and operated before July 2018. The corrected settlement varies in the range of 1600 - 25000 RON in the case of the control group and in the range of 1000 - 11000 in the case of the study group, with distributions showing a strong asymmetry to the right. The average level of the settlement (Table 5) in the case of the control group (md @ 4127 \pm 3668) is higher than in the case of the study group (m @ 2403 \pm 1808), the difference in tendency is statistically significant for a standardized value of the non-parametric comparison test Mann-Whitney Z = -4.95 and p < 0.001.

			Prola	pse		C ²
			yes	no	Total	
Group	Control group	Frequency	44	6	50	11.42**
type		Percent (%)	88.0%	12.0%	100.0%	
	Study group	Frequency	29	21	50	
		Percent (%)	58.0%	42.0%	100.0%	
Total		Frequency	73	27	100	21.16**
		Percent (%)	73.0%	27.0%	100.0%	
			Bleed	ding		
			yes	no	Total	
Group	Control group	Frequency	7	43	50	5.48*
type		Percent (%)	14.0%	86.0%	100.0%	
	Study group	Frequency	17	33	50	
		Percent (%)	34.0%	66.0%	100.0%	
Total		Frequency	24	76	100	27.04**
		Percent (%)	24.0%	76.0%	100.0%	
			Other sympt	toms (pain)		
			no	yes	Total	
Group	Control group	Frequency	30	20	50	5.88*
type		Percent (%)	60.0%	40.0%	100.0%	
	Study group	Frequency	41	9	50	
		Percent (%)	82.0%	18.0%	100.0%	
Total		Frequency	73	27	100	21.16**
		Percent (%)	73.0%	27.0%	100.0%	
			Throm	bosis		
			no	yes	Total	
Group	Control group	Frequency	47	3	50	3.09
type		Percent (%)	94.0%	6.0%	100.0%	
	Study group	Frequency	50	0	50	
		Percent (%)	100.0%	0.0%	100.0%	
Total		Frequency	97	3	100	88.36**
		Percent (%)	97.0%	3.0%	100.0%	

TABLE 3. The frequency of	^c cases according to the	associated symptomatology	(complication)
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Note: c2 – the value of the Chi-Square test for comparing frequency distributions, * - *level of significance p<0.05, ** - level of significance p<0.001.*

TABLE 4. Postoperative hospitalization

Postoperative hospitalization (days)	min	max	т	sd	md	sk	k	K-S
Control group	1	6	2.52	1.13	2.00	0.71	0.61	0.22**
Study group	1	4	1.74	0.80	2.00	1.01	0.77	0.26**

Note: m - arithmetic mean, sd - standard deviation, md - median value, sk - asymmetry coefficient, k - vaulting coefficient, K-S - the value of the Kolmogorov-Smirnov normality test

TABLE 5. Hospitalization statement corrected (values in RON; 1 EUR = 4,94 RON)

Corrected statement	min	max	m	sd	md	sk	k	K-S
Control group	1697	24274	5198.85	3667.85	4127.00	3.12	14.25	0,18**
Study group	1173	10815	2852.81	1808.14	2403.00	2.54	7.90	0.26**

Note: m – arithmetic mean, sd – standard deviation, md – median value, sk – asymmetry coefficient, k – vaulting coefficient, K-S – the value of the Kolmogorov-Smirnov normality test

DISCUSSION

The last 20 years have seen major changes in the techniques used in the treatment of HD. Thus, there is a clear trend towards mini-invasive and office tech-

niques (Rubber Band Ligation = RBL, Sclerosing Injections = SI, Infrared Coagulation = IRC) resulting in a very small percentage (below 10%) being hospitalized and operated in the hospital, this being mainly represented by cases with a high degree of prolapse (III or IV), rectal

bleeding with severe anemia, those with persistence of symptoms or recurrence after conservative or mini-invasive treatment, those whose surgical technique requires spinal or general anesthesia. In the last years in BECH the classic HE techniques (Milligan-Morgan or Ferguson), the ligation-resection technique (often using vascular sealing devices) were mainly applied, to which newer techniques were added such as Hemorrhoidopexy by stapling (PPH), THD-RAR or endoscopic RBL competing for priority. Thus, if 10 years ago HE represented over 90% of cases, in 2020 mini-invasive techniques reached over 50%, with a significant increase in PPH 31% and endoscopic RBL 7.5% but less, at only 9% of THD-RAR [1]. The explanation for this evolution is given by the patients' desire to benefit from methods accompanied by as little post-operative pain as possible, with a short hospitalization (possibly in an outpatient setting) and which allow for a faster recovery even if they assume a higher risk of recurrence. On the other hand, the increased price of consumables and the lack of their financing by the health system made this growth quite slow. But is this a real problem?

The THD technique (also originally called HAL = Hemorrhoidal Artery Ligation) appeared as a fortunate consequence of the meeting between the progression of medical thought and technological evolution, in 1995 the first series of cases being published by Morinaga et al [2]. The HAL technique used for the treatment of HD the idea of decreasing the blood flow in the internal hemorrhoidal plexuses by identifying and ligating the branches of the superior hemorrhoidal artery using a special anoscope with Doppler probe called Moricorn, thus achieving the reduction of hemorrhoids and the improvement of symptoms. To improve the results and reduce relapses in cases with advanced hemorrhoidal prolapse, Dal Monte and Tagariello [3] associate the THD technique with rectopexy (later called RAR – Recto-Anal Repair), which performs an ascent and fixation to the rectal muscle of the prolapsing mucosa by performing a resorbable running suture of the rectal mucosa. Ratto et al. [4] advocate a modification of the technique called DDD (Distal Doppler-Guided Dearterialisation) in which he ligates the arterial branches in the distal segment of the lower rectum where the branches are more superficial and safer to ligate, also using a using a marking artifice with the tip of the cautery. THD-RAR complies with the criteria of a mini-invasive technique, it does not affect the anatomy and physiology of the anal region of the anal region (as a result, late complications such as anal incontinence or postoperative stenosis are practically not cited for this type of intervention).

There have been many studies on the results of the HAL or THD-RAR method, but far fewer comparing the THD-RAR method with HE and only a few addressing the topic of cost-effectiveness [5-8]. From the point of

view of intrahospital surgical services, we should first of all compare HE with THD-RAR and PPH (RBL being the prerogative of office surgery and gastroenterology services). Lehur P et al. [5] compare the THD-RAR and PPH procedures in a randomized controlled multicenter study and find that they are equally safe and effective, THD-RAR being accompanied by a lower pain score and requiring fewer days for recovery but being followed by a higher number of recurrences (15% vs. 5% PPH), a higher reoperation rate (8 % vs. 4% PPH) and a slightly higher cost value. Although the rate of postoperative complications is comparable, it should be taken into account that the severity of complications from PPH is still higher (chronic pain, imperious defecation, rectal stenosis, fistula) which explains to some extent the decline in the frequency of this procedure in the healthcare systems of other countries [9]. Comparing THD-RAR with HE, most studies show that THD-RAR is superior to HE due to the reduced degree of postoperative pain, lower consumption of analgesics, lower rate of complications (tenesmus, hemorrhoidal thrombosis, acute fissure, persistent pain especially when rectopexy descends too low towards the skin edge of the anus), higher degree of patient satisfaction in the short term (however decreasing according to Walega et al. to 41% in patients with grade IV prolapse and in the long term), shorter length of hospital stay (even in "day hospitalization"), faster return to activity (less than 7 days for THD and more than 2 weeks for HE, a fact also confirmed by our study), comparable recurrence rate after Dal Monte of 3.7% for grade III and 11% for grade IV over 3 years, or higher according to Consalvo et al. (14.7% for THD-RAR vs. 4.67% for HE) [3,10-17]. An interesting aspect, observed by Scheyer et al. and confirmed in his study by Symeonidis et al, is that in THD-RAR the success rate was higher in patients in whom the dominant symptom treated was bleeding and then pain or itching, while whereas in HE the success rate was higher for patients whose dominant symptom was prolapse [18, 19]. We also obtained the same results from which a higher frequency of cases treated by THD-RAR for rectal bleeding (34% versus 14%; p<0.05) and those treated for prolapse by HE (88% vs. 58%; p<0.001). It would be much more practical to specify in the Goligher classification the circumferential extent of the prolapse and the size of the external hemorrhoidal component. From the point of view of the anatomical type of Hemorrhoids, it can be observed that the THD-RAR method was performed with predilection for internal Hemorrhoids, because it addresses exclusively this component. Studying the degree of prolapse, in cases operated by THD-RAR, grade III prevailed, while in cases operated by HE, grade IV prevailed.

From a demographic point of view, in our study there was a male predominance in both groups (66%),

and in terms of age, the mean age was statistically significantly higher in the THD-RAR group, reflecting the lower addressability of patients elderly for this method for financial reasons. Operative time was longer for HE versus THD-RAR (mean 48 versus 56 min with no significant influence on costs). The significantly longer postoperative hospital stay in the OH group compared to the THD-RAR group (2.52 versus 1.74 days; p < 0.001), obviously influenced the hospitalization expenses (2403 versus 4127 RON; p< 0.001). We are aware that we cannot cover exactly all the components that contribute to the final cost, but by referring to the actual bills (those applied to patients and settled by the house) and to the correction of costs according to their change over time we tried to get as close as possible updated values up to date. We used Postoperative Hospitalization in the calculation because this parameter is the one that is really influenced by the type of operation. The associated interventions (for Fissure, Mariscus, Polyps) were significantly equal in the two groups and they did not significantly influence the operating costs or the length of hospitalization. The purpose of conducting this study was not only the statistical evaluation of hospitalization costs and the materials used in the two batches, but also the actual calculation of the real costs involving the two types of surgery. Finally (Table 6) when calculating the actual total expenses (for Operation - related to depreciation of equipment and instruments and consumables, for Hospitalization - related to accommodation and meals and Social expenses - related to the number of days of medical leave) a value of 6532 RON is observed for HE which obviously exceeds the calculated value of 5159 RON for THD-RAR. Another element that should be discussed is the recurrence rate in terms of the number of days of incapacity for work due to new onset of the disease or the need for a new hospitalization in order to re-intervention for HD. In our study, the recurrence rate (5 cases at THD versus 3 cases at HE) was not significantly higher, 4 out of 5 being reoperated (1 with RBL, 2 with THD-RAR, 1 with hemi-Whitehead).

Table 7 shows the ideal criteria of a surgical intervention for HD and which are largely met by the THD-RAR technique. The accessibility criterion could be overcome by the contribution of private units in the treatment of HD and changing the policy of state hospitals regarding the provision and training of specialists in this pathology, who know each technique. The criterion regarding relapses was improved by associating to the initial THD technique the RAR method which increased the efficiency in hemorrhoids accompanied by high degrees of prolapse III-IV, to which a better selection of cases operated by the THD-RAR technique could be added (avoiding those with grade IV prolapse in the crown or those with associated representative external

Costs	THD	HE
I – Procedural Costs		
Apparatus amortization	260	-
Instruments amortization	37	110
Anoscop and wires (single use)	1576	-
II – Hospitalization costs		
Recalculated Hospitalization Bill	2403	4127
III – Social Costs (SL days)		
SL for hospitalization period	228	330
SL upon discharge	655	1965
Total =	5159	6532

TABLE 7. Ideal criteria for the surgery of Hemorrhoid Disease

 (HD)

Criteria	THD	HE
1. Mini-invasive method	+	-
2. Office method or suitable for one-day	+	-
admissions		
3. Method that is accompanied by a small degree	+	-
of pain		
4. Reduced level of complications	+	+/-
5. Rapid return into normal activity	+	-
6. High efficiency (low level of Recurrences –	+/-	+
Bleeding, Prolapse)		
7. High accessibility to the method	-	+/-
8. Low price	-	+/-

component), or resorting to repeating the method where evolution requires it. Our study shows that the last criterion regarding the cost of the method was unfairly considered against the THD-RAR method. Thus, if we do the integrated calculation by cost groups, we notice that if the first category (Costs for Operation) THD-RAR has higher values compared to HE, in the second and third categories (Hospitalization Costs and Social Costs) the costs for patients with HE are higher, finally covering the costs of the intervention through the THD-RAR procedure and being even higher by 1373 RON.

CONCLUSION

Although it seems an attractive method in terms of advantages, the THD-RAR technique for the treatment of HD has expanded more slowly and in a narrower area, this being explained primarily due to the price. On a more superficial thinking, one might say that this is a valid reason. Our study shows that if we make a more careful calculation and subtract from the amortization expenses (device and anoscope), in detriment of THD-RAR, the savings made from hospitalization expenses and the social expenses (duration of reintegration into activity) higher in the procedure of HE versus THD-RAR, then the balance will tilt towards THD-RAR. So yes, the THD-RAR technique can be considered a cost-effective operation over the HE technique. The introduction of the THD-RAR method into the therapeutic arsenal of DH is to the benefit of both health institutions and the patient, as it should take its place both in the therapeutic protocols of each health facility and in the national diagnostic and treatment guidelines. On the other hand, it is correct and deontological to inform the patient about all the treatment methods available, exposing him to the advantages and disadvantages of each and thus making it possible for the choice of the most

Conflict of interest: none declared *Financial support:* none declared

suitable method to be made together with the patient and not as a subjective opinion of the attending physician. In this context, a correct presentation of the real situation is necessary before the decision-making forums that lead the health units in order to make it possible to finance and implement this method in the operative routine, in such a way that all patients who have an indication can benefit from it, regardless of their financial possibilities.

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