COMPARISON OF THE COST-EFFECTIVENESS OF THREE APPROACHES TO SCREENING FOR AND TREATING SIGHT-THREATENING DIABETIC RETINOPATHY


SUMMARY - The purpose of this study was to analyse and compare the costs involved in screening for and treating sight-threatening diabetic retinopathy in three different clinical settings. In the first setting, diabetologists screened using ophthalmoscopy and color photography, according to the St. Vincent Declaration guidelines, and selected patients for further assessment by a visiting ophthalmologist and for treatment in another hospital. In the second setting, all patients were regularly referred to ophthalmologists, either in the same hospital or elsewhere, for all aspects of eye care. In the third setting, screening was done again with ophthalmoscopy alone by diabetologists who followed the St. Vincent Declaration guidelines; however, further assessment and treatment were carried out in the eye department of the same hospital. Costs to the Italian National Health Service and to patients were calculated per screening performed and per patient subjected to laser treatment as a result of screening. A sensitivity analysis was then performed to simulate the costs of standardised patient populations going through the three different settings. It is concluded that absolute costs would be lower, both for the Italian National Health Service and for patients, if screening, assessment and treatment were all carried out in the same hospital. Equipment a diabetic clinic specially for screening would not be more expensive than delegating eye care to external parties, even for a hospital without an eye department. Moreover, delegating eye care more than doubles costs for patients. Screening for, assessing and treating sight-threatening diabetic retinopathy may be a cost-effective procedure for society as a whole in Italy. Diabetes & Metabolism 1999, 25, 44-53

RÉSUMÉ - Rapport coût/bénéfice de trois approches du dépistage et du traitement des rétinopathies diabétiques menaçantes. Ce travail a pour but d’analyser et de comparer les coûts induits par le dépistage et le traitement des rétinopathies menaçantes selon trois approches différentes. Dans le premier centre, les diabétologues ont pratiqué un dépistage basé sur l’ophtalmoscopie et une photographie couleur selon les recommandations de la déclaration de Saint-Vincent, et les sujets ainsi sélectionnés ont été référés à un ophtalmologiste puis pour traitement à un autre centre hospitalier. Dans le second centre tous les patients étaient référés à un ophtalmologiste dans le centre ou en dehors pour prise en charge de tous les problèmes oculaires. Dans le troisième centre les diabétologues assuraient une ophtalmoscopie seule mais référaient ensuite les patients dans le département d’ophtalmologie du même centre hospitalier. Les coûts induits par le dépistage et le traitement laser des sujets dépistés ont été calculés pour le Service National de Santé Italien. Une simulation de coût selon ces trois stratégies a été appliquée à l’ensemble des sujets diabétiques en Italie. Notre conclusion est qu’il est moins coûteux, pour le service de santé italien comme pour le patient, de réaliser l’ensemble de la prise en charge ophtalmologique dans un même hôpital. Il n’est pas plus coûteux d’équiper un hôpital d’un centre ophtalmologique que de déléguer la prise en charge en externe, y compris pour un hôpital ne disposant pas de service d’ophtalmologie. Déléguer cette prise en charge engendre une dépense double pour le patient. L’organisation du dépistage, de la prise en charge et du traitement des rétinopathies diabétiques menaçantes l’acuité visuelle peut constituer un rapport coûts-bénéfices significatif pour l’ensemble des dépenses de santé personnelles et collectives en Italie. Diabetes & Metabolism 1999, 25, 44-53

Mots-clés : Rétinopathie diabétique, cécité, dépistage, économie de santé, analyse coût-bénéfice.

ORIGINAL ARTICLE

Key-words: Diabetic retinopathy, blindness, screening, health economics, cost-benefit analysis.

Abbreviations : Italian National Health Service = INHS ; sight-threatening diabetic retinopathy = STDR ; diabetic retinopathy = DR ; St. Vincent Declaration = SVD.

Screening for sight-threatening diabetic retinopathy (STDR) is a cost-effective means of preventing diabetes-related blindness [1], which remains a leading cause of visual loss in most industrialised countries [2-4]. Guidelines were agreed upon by the Retinopathy Working Party in 1990 to encourage a uniform approach to screening and monitoring of outcome in Europe [5], as a step towards implementing the St. Vincent Declaration (SVD) [6]. However, operators and procedures vary widely among diabetes centres in which screening is performed, depending on local resources and preferences.

The purpose of this study was to compare the costs of screening for and treating STDR in 3 centres with differing characteristics. In two centres, screening was performed by diabetologists in the diabetic clinic, according to SVD guidelines, although the referral policies for patients requiring further ophthalmic care were different. In the third centre, all aspects of eye care were carried out by ophthalmologists outside the diabetes clinic. Costs were calculated from the perspective of both the Italian National Health System (INHS), which covers all direct medical care but not disability benefits, and patients.

**MATERIALS AND METHODS**

**Screening procedures** – The study was carried out in 3 centres in which screening for diabetic retinopathy (DR) had been regularly performed in the years 1993-1994. Centre A, based in the main Turin teaching hospital, is a relatively small academic outpatient clinic with a turnover of 500 to 700 patients/year. Screening was performed by diabetologists according to the procedure described in the SVD protocol [5], by both indirect and direct ophthalmoscopy and by colour photography of two 50° fields per eye, one centred temporal to the macula with the field margin tangential to the nasal margin of the optic disc, and the other of the nasal field centred temporal to the macula with the photographic margin covering up to one disc diameter temporal to the disc. DR was classified according to the SVD protocol [5], by both indirect and direct ophthalmoscopy alone in Centre A, the costs were worked out by simulating that this Centre had not purchased a fundus camera and had referred patients externally for FAGs at the current rate for 15 min visit was applied. The cost of laser treatments for Centre A was calculated as the fee actually paid by the INHS on an outpatient basis at IIt. 110,000/session. Other cost calculations included consumables and depreciation rates of equipment for screening, fluorescein angiograms (FAGs) and photoocoagulation, based on purchase costs with a discount rate of 8 %, according to the recommendations issued by the Italian Ministry of Health (Art 20, law No. 67/1988). The following lifespans were assumed for use of equipment: 10 years from new for funduscamera benches, laser photoocoagulators and general office furniture; 5 years for projectors to measure visual acuity and computers; and 4 years for ophthalmoscopes and camera bodies. When considering the hypothesis that screening had been done by ophthalmoscopy alone in Centre A, the costs were worked out by simulating that this Centre had not purchased a fundus camera and had referred patients externally for FAGs at the current rate for the INHS of IIt. 90,000 per test. Overhead costs were not calculated.

Patient costs were calculated by administering a questionnaire to randomly selected groups of 50 patients for each centre. Details of distances travelled to reach the medical facilities from home or work, means of transportation, travelling and waiting times and any other expenses incurred were recorded. For patients using public transport, the relevant fares were recorded, while for those using private cars an average running cost of IIt. 500/km was applied, as derived from data relevant to the 20 most commonly sold cars in Italy [7]. To these direct expenses was added the cost-opportunity of time loss, as calculated either on the basis of the patients’ salaries (12,000 IIt/hr in the case of housewives) or by requesting those who were self-employed, retired or unemployed to rate one hour of their time on a scale of: 0, 5,000, 10,000, 15,000, 20,000, 25,000 or another amount in IIt.

**Statistical calculations** – A standard worksheet (Excel for Windows, Microsoft, Seattle, WA) was used for calculations. Differences among the populations of the 3 centres were analysed by the Kruskal-Wallis test (analysis of variance) and then checked...
between groups by the Mann-Whitney test. The chi-square test was applied in the case of noncontinuous variables.

# RESULTS

The characteristics of the patient populations screened in the 3 centres are summarised in Table II. Sex, Type 1 versus Type 2 diabetes, and prevalence of known hypertension were similar, whereas patients in Centre B were older, had longer disease duration and were more frequently on insulin treatment than those in Centres A and C.

The presence and severity of DR at screening in the three centres is shown in Table III. More patients were classified as having no retinopathy, and less as having background retinopathy, in Centre B than in Centres A and C (p < 0.001 for all comparisons). Centre C reported more cases of maculopathy and proliferative DR than Centres A or B, but the difference was not statistically significant. There was a trend towards more patients treated by laser in Centre B.

Table IV shows the numbers of screening sessions in Centres A and C, and of ophthalmological consultations, fluorescein angiograms (FAG) and laser treatment sessions in all three Centres. No screenings are reported for Centre B because, by definition, eye care was done by outside referrals in this case. FAG was used more extensively in Centre B for all degrees of retinopathy, and in Centres B and C for the assessment of proliferative DR, than in Centre A. Patients in Centre B underwent a greater number of treatment sessions.

Table V details the total costs per screening procedure incurred by the INHS and patients, including the
costs of photocoagulations performed as a result of screening in each centre.

Since the costs were divided among the patients actually seen in the 3 centres, a sensitivity analysis was performed to work out the costs of screening in the 3 centres, assuming that they saw similar numbers of patients. Given their structural characteristics, the assumptions were made that Centres A and C could see a maximum of 1,500 and 2,000 patients/year respectively without generating extra costs to enlarge...
their facilities, whereas Centre B could not reasonably screen fewer than 1,000 patients/year. Figure 1 shows that the total costs of in-house screening by ophthalmoscopy (Centres A and C) would be lower than when patients were referred to external ophthalmologists (Centre B). In particular, they would be lower in Centre A than in Centre B, even if ophthalmoscopy and photography were both carried out in 1,000 or 1,500 patients/year.

Since there were more old-age pensioners in Centre B, the income lost per consultation (Itl/min 110) was lower than in Centres C (Itl/min 141) or A.
(ItL/min 187), where more patients were still in active work. Hence, the total costs were further standardised using the weighted average of individual cost-opportunities calculated among patients of the 3 centres.

Figure 2 shows that screening organised as part of routine visits compares even more favourably with outside referral when the direct costs of patients are taken into account.

The actual costs per treated patient were higher in Centre A whether photography (ItL 1,619,428), ophthalmoscopy (ItL 1,631,317) or both (ItL 1,813,901) had been used to screen than in Centres B (ItL 1,016,176) and C (ItL 1,313,072). This remained true even when the costs were corrected by standardising the numbers of patients screened in each centre (Fig. 3). This, however, reflects the fact that the younger patients in Centre a had required less treatment and had lost more money to attend screening and treatment sessions, thus increasing unit costs. The sensitivity analysis was then further standardised by simulating that each centre had treated the same percentage of patients (i.e. the overall average of patients treated, 159/2,069 = 7.68 %) and that the patient costs had been the same in the three centres (again, by taking

### Table V. Costs of resources per screening (in ItL) to the Italian national health service and the patients, to screen for and treat DR in the 3 centres.

<table>
<thead>
<tr>
<th>Centre</th>
<th>Screening method</th>
<th>Labour</th>
<th>Consumables</th>
<th>Mortgage rates</th>
<th>Laser treatment</th>
<th>Total Screeing</th>
<th>Laser</th>
<th>Total</th>
<th>Total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Photography</td>
<td>10,159</td>
<td>3,723</td>
<td>16,630</td>
<td>27,923</td>
<td>58,435</td>
<td>12,373</td>
<td>6011</td>
<td>18,384</td>
</tr>
<tr>
<td></td>
<td>Ophthalmoscopy</td>
<td>10,509</td>
<td>973</td>
<td>6,881</td>
<td>27,923</td>
<td>46,286</td>
<td>12,560</td>
<td>6011</td>
<td>18,571</td>
</tr>
<tr>
<td></td>
<td>Photography + ophthalmoscopy</td>
<td>15,859</td>
<td>3,723</td>
<td>19,407</td>
<td>27,923</td>
<td>66,912</td>
<td>13,121</td>
<td>6011</td>
<td>19,132</td>
</tr>
<tr>
<td>B</td>
<td>Ophthalmoscopy</td>
<td>12,310</td>
<td>3,908</td>
<td>2,671</td>
<td>19,470</td>
<td>38,359</td>
<td>21,299</td>
<td>5303</td>
<td>26,602</td>
</tr>
<tr>
<td>C</td>
<td>Ophthalmoscopy</td>
<td>11,494</td>
<td>5,260</td>
<td>8,496</td>
<td>28,463</td>
<td>53,713</td>
<td>10,024</td>
<td>6740</td>
<td>16,764</td>
</tr>
</tbody>
</table>

**Fig. 1.** Sensitivity analysis of costs per screening in the 3 centres, by modifying the number of patients seen each year.

**Fig. 2.** Sensitivity analysis of costs per screening in the 3 centres, corrected by patient cost-opportunity (145 ItL/min) and by the number of patients seen each year.

**Fig. 3.** Sensitivity analysis of costs per patient treated in the 3 centres, by modifying the number of patients seen each year.
### TABLE VI. Costs per screening (in ItL) in the 3 centres, standardized by 1,000 screenings/year, percentage of patients treated as a result of screening (7.68%) and costs to patients (145 ItL/min).

<table>
<thead>
<tr>
<th>Centre</th>
<th>Screening method</th>
<th>Cost per screening to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>INHS</td>
</tr>
<tr>
<td>A</td>
<td>Photography</td>
<td>50,874</td>
</tr>
<tr>
<td></td>
<td>Ophthalmoscopy</td>
<td>46,145</td>
</tr>
<tr>
<td></td>
<td>Photography + ophthalmoscopy</td>
<td>57,963</td>
</tr>
<tr>
<td>B</td>
<td>Ophthalmoscopy</td>
<td>49,579</td>
</tr>
<tr>
<td>C</td>
<td>Ophthalmoscopy</td>
<td>58,133</td>
</tr>
</tbody>
</table>

INHS = Italian national health service.

### TABLE VII. Costs per screening (in ItL) in the 3 centres, standardized by 1,500 screenings/year, percentage of patients treated as a result of screening (7.68%) and costs to patients (145 ItL/min).

<table>
<thead>
<tr>
<th>Centre</th>
<th>Screening method</th>
<th>Cost per screening to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>INHS</td>
</tr>
<tr>
<td>A</td>
<td>Photography</td>
<td>48,102</td>
</tr>
<tr>
<td></td>
<td>Ophthalmoscopy</td>
<td>44,999</td>
</tr>
<tr>
<td></td>
<td>Photography + ophthalmoscopy</td>
<td>54,728</td>
</tr>
<tr>
<td>B</td>
<td>Ophthalmoscopy</td>
<td>40,946</td>
</tr>
<tr>
<td>C</td>
<td>Ophthalmoscopy</td>
<td>49,340</td>
</tr>
</tbody>
</table>

INHS = Italian national health service.

### TABLE VIII. Costs per patient treated as a result of screening (in ItL) in the 3 centres, standardized by 1,000 screenings/year, percentage of patients treated as a result of screening (7.68%) and costs to patients (145 ItL/min).

<table>
<thead>
<tr>
<th>Centre</th>
<th>Screening method</th>
<th>Cost per screening to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>INHS</td>
</tr>
<tr>
<td>A</td>
<td>Photography</td>
<td>1,044,256</td>
</tr>
<tr>
<td></td>
<td>Ophthalmoscopy</td>
<td>903,240</td>
</tr>
<tr>
<td></td>
<td>Photography + ophthalmoscopy</td>
<td>1,189,767</td>
</tr>
<tr>
<td>B</td>
<td>Ophthalmoscopy</td>
<td>1,142,926</td>
</tr>
<tr>
<td>C</td>
<td>Ophthalmoscopy</td>
<td>874,797</td>
</tr>
</tbody>
</table>

INHS = Italian national health service.
the weighted average of individual costs at ItL
145/min). The resulting costs of screening and treating
standardised patient populations in the three different
setups are shown in Tables VI to IX.
The analysis of practices and costs in the three diabetic clinics suggests that some of the differences found derive from the baseline organisation of the setups, whereas others are presumably a result of the procedures chosen to screen for STDR (Table I). Among clinic-derived differences, patient characteristics (Table II) were a main confounding factor, as the fairly large sample populations examined showed that patients attending Centre B were older, had longer duration of diabetes and were more frequently on insulin than those in Centres A or C. All of these are well-known risk factors for STDR [8], while older age would reduce the costs borne by the patients to attend screening and treatment sessions. Indeed, when interviewed, some retired patients even assigned a positive monetary value to the time spent in clinics, as this represented almost welcome breaks from daily routine. As a final result, costs in Centre B were diluted among more patients requiring laser treatment at lower personal loss of income in a national insurance-based health system. No attempt was made to compare metabolic control in the 3 centres, another main determinant of STDR prevalence and incidence [8], because different methods and reference values were used for the routine measurement of glycated haemoglobin. In any event, the standards of diabetes care in the 3 clinics were considered to be similar, although this assumption can only be substantiated on the basis of the high levels of patients screened for DR in all of them (see Table II).

Heterogeneous screening policies in the 3 centres accounted for even more differences, extending to assessment and treatment of STDR, which made it necessary to standardise the cost components involved in order to make them comparable. Although the district hospital to which Centre B belongs has its own eye department, only 46% of the patients were screened in it. The other 54% sought the advice of external ophthalmologists, mostly working for the INHS, based near the patients residences. A small proportion of these patients consulted an ophthalmologist on a fee-for-service basis, but the costs involved were calculated as if they had availed themselves of national health insurance. It is safe to assume that most of these ophthalmologists did not follow SVD screening guidelines. Indeed, some did not even dilate pupils prior to ophthalmoscopy, so that many cases of mild non-proliferative DR were misclassified as “absence of DR” (meaning “non-clinically-significant DR”) (Table III). On the other hand, a number of FAGs may have been performed as an adjunct screening procedure rather than as a guide to treatment in cases already classified as STDR, which was the common policy in Centres A and C (Table IV). Centre A, on the other hand, is a small academic setting with a specific interest in diabetic retinopathy, in which special efforts are made to identify mild lesions, such as isolated microaneurysms, which might be overlooked by more clinically oriented practitioners. This may explain why the percentage of patients classified as having “background DR” was higher, and that of “non-retinopathies” lower, in this Centre as compared to the other two. Finally, Centre C has a long tradition of screening for DR and of collaborating with the eye department in the same hospital, and its rates of non- and mild retinopathies were somewhere between Centres A and B.

Much less heterogeneity was found in the case of STDR, as the rates of maculopathy and proliferative DR were similar in the 3 centres, in accordance with previous reports [9, 10] that specificity is higher when screening for STDR than for less severe retinopathy. The prevalence of STDR severity was similar to [11] or higher than [12] that reported in previous cross-sectional surveys of northern Italian populations. Even though there was no “gold standard” against which to validate the diagnoses made, this suggests satisfactory

**DISCUSSION**

[Table IX]: Costs per patient treated as a result of screening (in €) in the 3 centres, standardized by 1,500 screenings/year, percentage of patients treated as a result of screening (7.68%) and costs to patients (145 €/min).

<table>
<thead>
<tr>
<th>Centre</th>
<th>Screening method</th>
<th>Cost per screening to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>INHS</td>
</tr>
<tr>
<td>A</td>
<td>Photography</td>
<td>987,357</td>
</tr>
<tr>
<td></td>
<td>Ophthalmoscopy</td>
<td>879,060</td>
</tr>
<tr>
<td></td>
<td>Photography + ophthalmoscopy</td>
<td>1,123,364</td>
</tr>
<tr>
<td>B</td>
<td>Ophthalmoscopy</td>
<td>943,913</td>
</tr>
<tr>
<td>C</td>
<td>Ophthalmoscopy</td>
<td>742,478</td>
</tr>
</tbody>
</table>

INHS = Italian national health service.
overall sensitivities and specificities in all 3 centres, which had screened between 94 % and 100 % of their patients at least once within the 2-year period considered (Table II). In particular, we feel that it is safe to assume that the overall sensitivity of the screening procedures was greater than 60 %, a level above which computer simulation models suggest that additional gains in sight-years saved and budgetary savings reach a plateau [13].

More FAGs and photocoagulation were performed as a result of screening in Centre B (Tables III and IV). This may have been due in part to higher age, duration of diabetes and the rate of insulin treatment for patients in this Centre (Table II), and in part to a more liberal use of assessment and treatment procedures in a non-standardised setting. It was not possible, in any event, to organise retrospective auditing of the diagnostic and therapeutic procedures carried out. It should be noted, too, that a number of patients with no or only mild background retinopathy were referred for consultation, and that 3 received laser treatment for reasons other than STDR.

Preferred practice and standardised procedures for the early detection of STDR have been agreed upon both in North America [14] and Europe [5]. Many economic analyses have shown that the expenses involved in detecting and treating a patient with STDR are much lower than the costs of disability pensions and other benefits that would need to be paid should he/she become blind. A high cost-effectiveness ratio was calculated in earlier surveys [15] and then confirmed on a nationwide scale in the U.S.A., using computer-based simulations [16]. Finally, it has been calculated that screening for STDR, with expenses of US$ [3], 190 per quality-adjusted life-year gained, is the most cost-effective medical procedure known today [1].

This study represents the first cost analysis of the procedure recommended in Europe by the SVD working group for the prevention of diabetes-related blindness [5]. Assuming that all cases of STDR were properly detected and that laser treatment is a valid proxy for avoiding blindness, it is also the first cost-effectiveness assessment of screening for STDR in Italy. It demonstrates that applying the SVD procedure within the routine workup of outpatient diabetic clinics does not increase expenses for the national health system and saves patients considerable time and money. Even though diabetes units need to be specially instrumented with dedicated ophthalmoscopes and/or funduscameras, the investment costs are levelled out for screening turnover rates as low as 1,000 to 1,500 patients/year, which represent a reasonable workload for most mid-sized diabetic clinics in Italy and possibly in the rest of Europe.

There are no precise calculations of the direct and indirect costs of social security and related benefits for the visually handicapped which are not borne by INHS but by other agencies of the Italian government. Based on current pension rates and other allowances or benefits, a likely estimate is that a blind person receives between 20 and 30 million ItL every year from the Italian state. The one-off cost for the INHS of detecting and treating a patient with STDR was well below 2 million ItL, even in Centre A, the most expensive of the 3 settings investigated (Fig. 3). However, it would not be realistic to assume that all patients treated as a result of screening would become blind otherwise. It remains to be established how many patients can actually be saved from blindness by screening, and how many years they would survive receiving disability benefits. Historical series suggest that about 50 % of eyes with proliferative diabetic retinopathy would become blind within 5 years of diagnosis if left untreated [17], while more than 90 % of blindness could be prevented by timely laser photocoagulation [18,19], the benefits of which may persist for 15 years or longer [20]. The success rate of treatment for maculopathy is not precisely known, but at least 50 % of blindness can presumably be prevented at 5 years [18]. Obviously, comparisons today cannot be made between no treatment versus optimal treatment, but rather between late as opposed to timely photocoagulation. This complicates matters, because the outcome of not screening and leaving detection of STDR to random consultations and/or the onset of visual symptoms is not known. The Diabetic Retinopathy Study, during which laser treatment was applied somewhat late and/or not according to current guidelines, showed that more than 20 % of eyes with proliferative DR went blind in 5 years [21], while fewer than 5 % lost vision if treated according to Early Treatment of Diabetic Retinopathy Study criteria [18]. With respect to how long disability pensions would need to be paid for, Klein and co-workers reported that 55.9 % of patients with diabetes diagnosed before age 30, and 30.6 % of patients with older-onset diabetes, were alive 5 years after their vision had dropped below 20/200 [22], i.e. after they reached eligibility for legal blindness in America or Italy. Trautner et al. [23], over a shorter observation period, reported an overall relative risk of mortality of 2.253 when diabetes was the only cause of blindness.

In conclusion, these results suggest that, when comparable patient populations are seen, the costs to both the national health system and patients are lower if screening for STDR is performed in a diabetes clinic within a hospital equipped to provide further ophthalmic assessment and laser treatment. Not screening patients in the diabetic clinic and referring them to external ophthalmologists, even if some of the patients choose to go to an eye department within the same hospital, is slightly more expensive to the health system and hugely so for the patients themselves. For a diabetic clinic based in a hospital without an eye department to be equipped with a funduscamera and
screen for colour photography and/or ophthalmoscopy according to the Retinopathy Working Party SVDpro-
tocols [5] would not make the procedure more expensive for the health service, while saving patients con-
siderable amounts of money.

In Italy, as elsewhere, there are sight-years and public funds to be saved when screening for STDR, a
procedure which can satisfy the sometimes conflicting ethics of health-care providers and health administra-
tors.

Acknowledgments − A. Rizzitiello was an undergraduate stu-
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