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The effect of pneumatic trabeculoplasty on intraocular pressure: The results of a 6-month, open-label, multicenter study

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PURPOSE. *To evaluate the effects of pneumatic trabeculoplasty (PNT) in ocular hypertension and glaucoma subjects.*
METHODS. *A total of 63 consecutive subjects, either treated (79%) or untreated (21%), with intraocular pressure (IOP) between 20 and 25 mmHg were enrolled; the eye with higher IOP (or, in case of identical IOP, worse visual field) was treated with PNT, with the fellow eye used as control. Subjects underwent a baseline evaluation the day before treatment, two PNT treatments at day 0 and 7, visits at day 1, 8, 14, and at each month until the end of the study, which lasted 6 months. Safety was addressed at all visits; an IOP curve (at 8 and 10 AM, 2 and 4 PM) was obtained at baseline and during monthly visits.*
RESULTS. *In PNT eyes, baseline IOP was 22.2±1.6 mmHg. Following PNT a statistically significant reduction of IOP occurred at all visits ($p<0.0001$), with a mean decrease ranging from –2.7±2.5 (–11.9±10.8%) to –3.6±2.6 mmHg (–16.0±11.6%); mean reduction was 12.8±11.5%. Although IOP diminished also in the control eyes after baseline ($p<0.05$), the change in IOP was significantly higher in PNT group at each visit ($p<0.05$). Mild side effects were experienced by 76% of subjects and they all resolved without sequelae.*
CONCLUSIONS. *The results suggest the effect of this procedure in reducing IOP in glaucoma and ocular hypertensive subjects. (Eur J Ophthalmol 2008; 18: 922-8)*

KEY WORDS. *Glaucoma, Ocular hypertension, Intraocular pressure, Pneumatic trabeculoplasty, Pneumotrabeculoplasty*

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INTRODUCTION

In a large number of eyes undergoing laser-assisted in situ keratomileusis (LASIK), a significant reduction of intraocular pressure (IOP) was found after surgery (1). This may be an artifact due to the corneal thinning induced by the procedure, which reduces corneal rigidity, thus interfering with a correct assessment of IOP by means of applanation tonometry (2, 3). Nevertheless, it has been proposed by Avalos Urzua et al that, at least in certain cases, lower IOP readings after LASIK may reflect a real IOP reduction, as the force applied, via suction, to the peripheral cornea may strain trabecular meshwork thus augmenting outflow facility (4).

On the basis of these assumptions, an experimental device, called pneumatic trabeculoplasty (PNT), has been

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created to mimic the suction induced during LASIK. The PNT device is composed of a pump, plastic tubing (transmitting the pressure to the ring), and a disposable, sterile plastic ring, which is applied to the ocular globe in the region between the corneal periphery and the anterior part of the sclera, in the projection area of the trabeculum. During the procedure, a vacuum of about 50 mmHg is transmitted to the eye.

PNT has been recently approved in Europe for clinical use. Few data are available in literature: only two feasibility studies (4) and a pilot study (5). Although these studies seem to indicate an IOP-lowering effect of the procedure, the efficacy of PNT has not been fully demonstrated.

The aim of the present study is to provide further data for PNT in subjects with primary open-angle glaucoma (POAG) and ocular hypertension (OH).

METHODS

This prospective, multicenter, open-label trial involved four Italian University Eye Clinics: Chieti, Genova, Milan (San Paolo Hospital), and Verona. The protocol was approved by the Ethics Committee of each site and respected the tenets of the Declaration of Helsinki. All patients referred to the Glaucoma Units from June to September 2005 were considered for inclusion; after a full explanation of the aims and the procedures, 63 patients agreed to participate to the study and signed the informed consent.

Inclusion criteria were 18 years of age or more, presence of OH or primary open-angle, pseudoexfoliative, or pigmentary glaucoma, both treated and untreated, with IOP ranging between 20 and 25 mmHg. This IOP interval was arbitrarily chosen by the investigators in order to exclude the cases with severe IOP not sufficiently controlled.

Exclusion criteria included myopia <–6 diopters, present or past corneal, retinal, and uveal diseases, past ocular surgery (except for uncomplicated cataract surgery performed at least 6 months before inclusion), past argon laser trabeculoplasty, glaucoma with a mean defect <–12 dB, and uncontrolled systemic diseases.

Glaucoma was defined as an IOP >21 mmHg without medication (as measured on two consecutive occasions separated by an interval of at least 2 hours but not more than 12 weeks), glaucomatous visual field (on the basis of at least two reliable Humphrey 30-2 full-threshold tests, Carl Zeiss Meditec Inc., Oberkochen, Germany), and optic disc changes (evaluated by means of color stereophotographs) and/or retinal nerve layer (RNL) defects as evaluated by means of a scanning laser ophthalmoscope (6). OH was defined as IOP >21 mmHg without medication (measured as above) and normal visual field, optic disc, and RNFL.

The protocol consisted of a baseline visit (the day before the first PNT treatment), two PNT treatments at day 0 and day 7 (each PNT treatment comprised two vacuum applications), visits to assess the safety of the procedure (safety visits) at days 1, 8, 14, and monthly visits up to a follow-up of 6 months. At each visit the following examinations were done: best-corrected visual acuity, complete slit-lamp examination (including funduscopy after dilation with tropicamide 1%), and gonioscopy; subjects filled a questionnaire for symptoms; adverse events, changes in systemic treatments, and adherence to eye treatments were recorded. No alterations of IOP-lowering regimen were allowed during the study (no IOP-lowering medications were therefore added, subtracted, or switched in any case). Humphrey perimetry was performed at the beginning and the end of the study using the full-threshold 24-2 program. Gonioscopy was graded at each visit using the Shaffer classification: 0°=0; 10°=1; 20°=2; 30°=3; 45°=4.

A diurnal IOP curve was obtained at baseline and at each monthly visit; it consisted of four IOP readings at 8 and 10 AM and 2 and 4 PM (intervals of ±30 minutes were allowed). During safety visits, a single IOP measurement was taken at 8 AM. IOP measurements were performed by glaucoma specialists using a calibrated Goldmann applanation tonometer. An IOP measurement consisted of the mean of two or median of three readings (the third was taken only in the case of a difference of $\geq$2 mmHg between the first two). The investigators who measured IOP during baseline and monthly visit were different from those who performed PNT treatments and safety visits in order to maintain the masking of treated eye. For each patient, IOP was measured by the same investigator throughout the study.

At baseline, the worse eye was chosen to receive PNT and the fellow eye was used as a control. The worse eye was the one with higher IOP or, if it was identical in both eyes, worse mean defect at visual field.

PNT was performed with the patient in a supine position. Tetracaine 0.5% ophthalmic solution was administered, the lids were gently spread by the physician using his fingers, and a sterile PNT ring was centered on the cornea, using a moderate downward pressure to facilitate the initial attachment of the ring, as a vacuum of about 50 mmHg was applied to the ring. The vacuum lasted for 60 seconds and the procedure was repeated after a rest pe-

riod of 5 minutes. Successful attachment of the ring results in an impression into the sclera and the cornea, correlating to the shape of the ring and lasting for nearly 1 hour. After PNT, eyes were medicated with tobramycin 0.3% and diclofenac 0.1% eyedrops, which were also prescribed four times daily for 1 week.

Sample size calculation

The sample size estimate was based on the test for superiority. In the estimates below, the significance level was set to 5% and the power to 80%.

$$n = \frac{2[\Phi^{-1}(\alpha/2) + \Phi^{-1}(\beta)]^2 \sigma^2}{\Delta^2}$$

Based on previous experience the standard deviation for the intrapatient difference (σ) was inferior to 3.0 mmHg and the difference worth detecting (Δ) was 2.0 mmHg. This resulted in a total number of 50 subjects. Considering a maximum rate of discontinuation of 15%, an inclusion of 60 subjects was required.

Outcomes of the study and statistical analysis

The main outcome of the study was the IOP change in PNT-treated eyes. Mean IOP and IOP reduction (expressed both as mmHg and percentage decrease) were compared to the baseline and to control eyes at each monthly visit. The secondary aims were to calculate the percentage of patients achieving an IOP reduction <10%, ≥10%, >15%, >20%, and >25%, to evaluate the presence of factors influencing the effects of PNT, and to assess the safety of the procedure.

Data obtained from safety visits performed at days 1, 8, and 14 were not considered for analyses, which were conducted on daytime IOP curves alone (as obtained at baseline and during monthly visits). Changes in IOP were analyzed based on both the intent-to-treat population (including all available data) and the per-protocol population (including only the data of subjects who concluded the study).

IOP changes occurring in each group over time were compared to baseline by means of two-tailed *t*-test for paired data; the same test was used to compare IOP between PNT and control eyes at each visit. The relationship between IOP reduction and demographic and ophthalmic data was evaluated by means of regression analysis and, for categorical data, chi-square test. In order to explore a possible effect of regression to the mean, we tested the correlation between the mean individual IOP at baseline and at sixth month and the mean individual change of IOP throughout the study (7). Bravais-Pearson coefficient of correlation (ρ) was calculated for both PNT and control eyes.

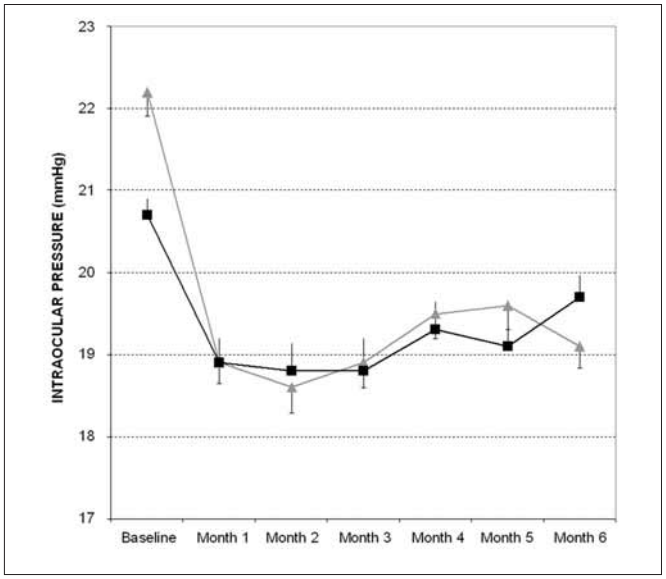

Fig. 1 - *Mean intraocular pressure readings at each monthly visit (bars represent standard errors). Triangles and grey lines, PNT eyes; squares and black lines, control eyes.*

RESULTS

A total of 63 subjects were enrolled in the study, which was concluded by 55 subjects (87%). Three subjects discontinued the study at month 1 (2) and 2 (1) due to insufficient IOP control (these patients had no changes in IOP after PNT and they asked the investigators to discontinue the study and to add a second IOP-lowering eyedrop); four for personal reasons at month 3. One patient was excluded for safety reasons (sudden IOP increase to 40 mmHg at day 8 without any other ocular change).

Demographic, ophthalmic, and perimetric data are summarized in Table I. No changes in visual field parameters, visual acuity, or Shaffer's classification of the angle occurred during the study. The effects of PNT on IOP are shown in Figure 1 and Table II. Mean IOP at baseline visit was 22.2±1.6 mmHg and PNT induced a significant IOP decrease to 18.9±2.7, 18.6±2.8, 18.9±3.1, 19.5±2.8, 19.6±2.8, and 19.1±2.2 at months 1, 2, 3, 4, 5, and 6, respectively ($p<0.00001$ at each visit compared to baseline). Mean individual IOP reduction was 3.1±2.8 mmHg compared to baseline, which corresponded to a percentage of

12.8%±11.5%. PNT eyes showed a statistically significant IOP reduction compared to control eyes at each visit except month 5 (Tab. II).

Table III stratifies subjects based on the percentage of IOP reductions compared to baseline. The treatment progressively lost efficacy over time (at month 5 and 6, about 50% of subjects had an IOP reduction less than 10%), although more than 20% of subjects obtained an IOP reduction higher than 25% at all study visits (compared to 0% in controls).

IOP reduction was also found in the control eyes: mean IOP went from 20.7±2.5 mmHg at baseline to 18.9±2.2, 18.8±2.7, 18.8±2.5, 19.3±2.6, 19.1±2.5, and 19.7±2.2 mmHg at months 1, 2, 3, 4, 5, and 6, respectively ($p<0.05$ at each visit compared to baseline, except for month 6, that had $p=0.07$, Tab. II). Apart from baseline, IOP in treated and untreated eyes was not different at any visit. During safety visits, IOP was 19.3±2.9, 18.9±3.0, and 19.2±3.3 mmHg in PNT eyes (days 1, 8, and 14), compared to 19.6±2.9, 18.7±2.1, and 19.3±3.0 mmHg in untreated eyes.

The above results were calculated from the intent-to-treat dataset; identical mean IOP results were obtained at all visits using a per-protocol analysis.

TABLE I - DEMOGRAPHIC, OPHTHALMIC, AND PERIMETRIC DATA OF STUDY PARTICIPANTS

Characteristics	**Values**	
Enrolled patients, n	63	
Study discontinuations, n (%)	8 (13)	
Causes		
Sudden raise in IOP	1	
Not sufficiently controlled IOP	5	
Personal reasons	2	
Age at inclusion, yr, mean ± SD (range)	66±10 (42–87)	
Race, n (%)		
Caucasian	62 (98)	
Black	1 (2)	
Male/female, n	36/27	
Iris color, n (%)		
Black	1 (2)	
Blue	7 (11)	
Brown	45 (72)	
Gray	1 (2)	
Green	8 (13)	
	PNT eye	**Non-PNT eye**
Right/left, n	38/25	25/38
POAG, n (%)	25 (40)	35 (56)
OH, n (%)	38 (60)	28 (44)
Duration of disease, yr, mean ± SD	5.3±3.8	5.3±3.8
Treatment, n (%)		
None	13 (21)	11 (17)
Prostaglandin analogues	31 (49)	16 (25)
Beta-blockers	22 (35)	18 (29)
Others	2 (3)	3 (5)
Snellen BCVA (beginning of the study)	0.94±0.15	0.95±0.12
Snellen BCVA (end of the study)	0.91±0.18	0.93±0.16
MD (beginning of the study), mean ± SD (range), dB	–2.44±3.59 (–11.72; +3.50)	–1.64±2.47 (-8.71; +2.19)
MD (end of the study), mean ± SD (range), dB	–2.71±3.78 (–12.92; +2.08)	–1.87±2.71 (–10.86; +2.38)

IOP = Intraocular pressure; POAG = Primary open-angle glaucoma; OH = Ocular hypertension; PNT = Pneumatic trabeculoplasty; BCVA = Best-corrected visual acuity; MD = Mean defect

The correlation between the mean of initial and final IOP and the change in IOP was negative for PNT eyes (ρ=–0.48) and negligible for control eyes (ρ=0.19). This seems to exclude a relevant regression to the mean.

Demographic, ophthalmic, and perimetric data were inspected as potential sources of difference in the IOP-lowering effect of PNT treatment. POAG eyes responded better to PNT than OH eyes (18.9%±8.5% vs 8.7±9.9%, p=0.0001). No differences were found for sex, age, iris color, angle grade, initial and final mean defect; no correlation between duration of the disease and PNT efficacy was found for either POAG or OH. Medical treatment was not a source of significant differences in the effects of PNT: although the group using prostaglandin analogues had higher IOP reductions (18.4%±7.5%) compared to beta-blockers (12.3%±9.9%) or combined treatments (12.7±2.9), this difference was not statistically significant (p=0.27 and 0.33, respectively). Also, intersite differences of efficacy were negligible.

Side effects occurred in 76% of subjects (Tab. IV); in the majority of cases they were minor and resolved within 2 weeks without sequelae. We had a case of corneal edema and of corneal abrasion lasting for 7 days and requiring no treatment. A patient had a sudden IOP increase to 40 mmHg the day after the second PNT repetition; he was treated with topical beta-blockers and acetazolamide, which were interrupted the day after, as IOP decreased to 18 mmHg.

TABLE II - MEAN RESULTS OF THE STUDY

	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Months 1–6
Patients, n	63	58	57	55	55	55	55	55
IOP, mmHg								
PNT	22.2 (1.6)	18.9 (2.7)	18.6 (2.8)	18.9 (3.1)	19.5 (2.8)	19.6 (2.8)	19.1 (2.2)	19.1 (2.8)
Non-PNT	20.7 (2.5)	18.9 (2.2)	18.8 (2.7)	18.8 (2.5)	19.3 (2.6)	19.1 (2.5)	19.7 (2.2)	19.0 (2.5)
p	<0.0001	0.92	0.97	0.80	0.64	0.16	0.55	0.95
Mean IOP decrease compared to baseline (mmHg)								
PNT		–3.3 (2.7)*	–3.6 (2.6)*	–3.3 (2.9)*	–2.7 (2.5)*	–2.8 (2.9)*	–3.1 (2.4)*	–3.1 (2.8)*
Non-PNT		–1.8 (2.1)†	–1.9 (2.5)†	–1.9 (2.7)†	–1.4 (2.3)†	–1.6 (2.5)†	–1.0 (2.2)‡	–1.7 (2.1)†
p		0.0001	<0.0001	0.001	0.001	0.056	0.005	0.0103
Mean IOP decrease compared to baseline (percentage)								
PNT		–14.4 (12.0)*	–16.0 (11.6)*	–13.9 (12.8)*	–11.9 (10.8)*	–10.5 (12.2)*	–12.4 (10.8)*	–12.8 (11.5)*
Non-PNT		–8.1 (9.6)†	–8.3 (13.3)†	–8.0 (13.9)†	–5.7 (12.8)†	–6.6 (14.2)†	–4.3 (8.3)††	–7.6 (10.8)†
p		0.0001	0.0001	0.0006	0.0024	0.0484	0.0076	0.0001

*p<0.00001 Compared to baseline.
†p<0.05 Compared to baseline; ††p=0.07.
IOP = Intraocular pressure; PNT = Pneumatic trabeculoplasty

TABLE III - RELATIVE FREQUENCY AND PERCENTAGE OF PATIENTS ACHIEVING DIFFERENT PERCENTAGE REDUCTIONS OF INTRAOCULAR PRESSURE COMPARED TO BASELINE

	PNT eyes					Non-PNT eyes	
	<10%	≥10%	>15%	>20%	>25%	<10%	10–15%
Month 1	20/58 (35%)	38/58 (65%)	38/58 (65%)	26/58 (45%)	13/58 (22%)	55/58 (95%)	3/58 (5%)
Month 2	17/57 (29%)	40/57 (71%)	37/57 (65%)	30/57 (53%)	22/57 (38%)	54/57 (95%)	3/57 (5%)
Month 3	21/55 (38%)	34/55 (62%)	28/55 (51%)	20/55 (36%)	18/55 (33%)	51/55 (93%)	4/55 (7%)
Month 4	23/55 (42%)	32/55 (57%)	20/55 (36%)	16/55 (29%)	13/55 (24%)	53/55 (96%)	2/55 (4%)
Month 5	27/55 (49%)	28/55 (51%)	23/55 (42%)	18/55 (33%)	13/55 (24%)	54/55 (98%)	1/55 (2%)
Month 6	27/55 (49%)	28/55 (51%)	26/55 (47%)	21/55 (38%)	12/55 (22%)	53/55 (98%)	2/55 (2%)

PNT = Pneumatic trabeculoplasty

DISCUSSION

The use of PNT in clinical practice has been recently approved by European regulatory authorities; as a consequence some European clinicians are using this device without a rigorous demonstration of efficacy. We conducted a prospective, open-label, multicenter study to provide further information on the effects of PNT.

PNT induced a mean IOP reduction of 12.8%±11.5%; this mean effect was superior to placebo (8) but inferior to the currently used medications (8) or laser treatments (9). Yet, it should be noted that, as the study protocol did not allow any change in IOP-lowering treatments, for about 80% of subjects who were under treatment the effect of PNT was additive.

Overall, large deviations from the average effect were found: a group of more than 20% of subjects constantly achieved IOP reductions of at least 25%, while those having an IOP reduction of less than 10% (corresponding to 2.2 mmHg in this study, which is within the error of measurement for tonometry) were about 30–40% during the first 3 months of follow-up and 40–50% for the remainder of the study. A total of 93–98% of untreated eyes had an IOP reduction of 10% or less, while the other 2–7% had IOP reduction between 11 and 15% (Tab. III).

IOP reduction was statistically higher in PNT eyes compared to non-PNT eyes at all visits except month 5, and percentage IOP reduction was significantly different in the two groups at all visits (Tab. II).

TABLE IV - SIDE EFFECTS OCCURRING AFTER PNEUMATIC TRABECULOPLASTY

Side effects	Subjects (%)	Duration, mean ± SD (range)
Conjunctival hyperemia	31 (49)	12 ± 20 d (1; 90)
Foreign body sensation	11 (17)	10 ± 13 d (1; 45)
Punctuate keratitis	8 (13)	7 ± 0 d
Blurred vision	7 (11)	1 ± 2 h (15 min–5 h)
Subconjunctival hemorrhage	5 (8)	5 ± 6 d (1; 14)
Burning	4 (6)	6 ± 6 d (1; 14)
Dry eye sensation	3 (5)	10 ± 6 d (1; 14)
Corneal abrasion	1 (2)	7 d
Corneal edema	1 (2)	7 d
Sudden IOP increase to 40 mmHg	1 (2)	1 d
Photophobia	1 (2)	1 d

IOP = Intraocular pressure.
d= days

In our 6-month follow-up, mild side effects occurred in three-quarters of subjects, but only three cases had more severe problems that resolved in less than 1 week without requiring any intervention apart from the use of eyedrops.

Our results confirm previous findings on the IOP-lowering effects (5) and side effects (4, 5) of this procedure, despite a different design of the study. As there are no reports validating the repetition of PNT at month 3 (as suggested by the manufacturers), we chose to perform it only at day 0 and 7, and we actually confirmed a peak in efficacy at months 2–3 and a partial loss of efficacy thereafter.

It was not possible to predict which subjects would better respond to PNT on the basis of demographic, ophthalmic, and perimetric data. As patients with POAG responded better than OH and were more commonly under treatment with prostaglandin analogues, we could suggest that the increase of trabecular outflow induced by PNT (Ceruti P, et al. Invest Ophthalmol Vis Sci 2006;47: E-Abstract 5483) might be synergic to the increase of uveoscleral outflow induced by prostaglandin analogues, although any theory on the mechanisms of action of PNT is speculative and needs to be rigorously verified in experimental settings (5, 10).

In this study we found a significant IOP decrease, compared to baseline, also in the control group, as previously described by Bucci et al (5). This result is confounding and may induce skepticism on the quality of our dataset. Possible explanations include increased compliance to treatment and regression to the mean. Adherence to treatment is generally improved under the conditions of a prospective study. The better response of POAG patients to PNT might be explained by the fact that, having a more aggressive medical regimen than OH, they could have been more prone to an improvement in compliance. The absence of a sham procedure was a limit of this study, because it would have brought out the compliance issues and the real effect of treatment. We explored the presence of a regression towards the mean according to Altmann (7); this test was negative, thus reducing the likelihood of an effect on our data.

Also, the presence of similar IOP readings between treated and untreated eyes (Tab. II) at follow-up may be explained by error in measurements. For each patient, IOP curves were collected by the same investigator in order to obtain less variable data. This evaluator was masked to treatment; anyway, due to the open-label design of the study, we cannot exclude the possibility of bias in IOP measurements.

Data on PNT are encouraging but still limited in number and quality. The studies by Avalos Urzua et al (4) and Bucci et al (5) showed that PNT can provide significant IOP reductions, but they lacked a rigorous design: control data were missing, IOP was not addressed by daytime curves, and (for the first two studies) PNT protocol was not scheduled.

All literature confirm that side effects due to PNT always resolved without sequelae (4, 5); but long-term information (possibly comparing PNT with other parasurgical procedures) is lacking. In our dataset, we did not find any significant change in visual fields at the end of the study. The perimetric effects of a transient IOP elevation have been very recently evaluated also by Chan et al, but their results were inconclusive due to the absence of control for learning effect (11).

Finally, data on long-term efficacy are needed and other important clinical issues should be clarified, in particular the duration of the efficacy of PNT treatment, the frequency of repetitions required to obtain a stable long-term IOP reduction (our data suggest the possibility of a repetition after 3 months), and the identification of subjects who better respond to this procedure.

No author had any proprietary interest in the products mentioned in this study.

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