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Patient initiated outpatient follow up in rheumatoid arthritis: six year randomised controlled trial

Sarah Hewlett, John Kirwan, Jon Pollock, Kathryn Mitchell, Maggie Hehir, Peter S Blair, David Memel and Mark G Perry

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Patient initiated outpatient follow up in rheumatoid arthritis: six year randomised controlled trial
Sarah Hewlett, John Kirwan, Jon Pollock, Kathryn Mitchell, Maggie Hehir, Peter S Blair, David Memel, Mark G Perry

Abstract

Objectives To determine whether direct access to hospital review initiated by patients with rheumatoid arthritis would result in improved clinical and psychological outcome, reduced overall use of healthcare resources, and greater satisfaction with care than is seen in patients receiving regular review initiated by a rheumatologist.

Design Two year randomised controlled trial extended to six years.

Setting Rheumatology outpatient department in teaching hospital.

Participants 209 consecutive patients with rheumatoid arthritis for over two years; 68 (65%) in the direct access group and 52 (50%) in the control group completed the study (P = 0.04).

Main outcome measures Clinical outcome: pain, disease activity, early morning stiffness, inflammatory indices, disability, grip strength, range of movement in joints, and bone erosion. Psychological status: anxiety, depression, helplessness, self efficacy, satisfaction, and confidence in the system. Number of visits to hospital physician and general practitioner for arthritis.

Results Participants were well matched at baseline. After six years there was only one significant difference between the two groups for the 14 clinical outcomes measured (deterioration in range of movement in elbow was less in direct access patients). There were no significant differences between groups for median change in psychological status. Satisfaction and confidence in the system were significantly higher in the direct access group at two, four, and six years: confidence 9.8 v 8.4, 9.4 v 8.0, 8.7 v 6.9; satisfaction 9.3 v 8.5, 9.3 v 7.7, 8.9 v 7.1 (all P < 0.02). Patients in the direct access group had 38% fewer hospital appointments (median 8 v 13, P < 0.0001).

Conclusions Over six years, patients with rheumatoid arthritis who initiated their reviews through direct access were clinically and psychologically at least as well as patients having traditional reviews initiated by a physician. They requested fewer appointments, found direct access more acceptable, and had more than a third fewer medical appointments. This radical responsive management could be tested in other chronic diseases.

Introduction

Patients with chronic inflammatory diseases such as asthma, inflammatory bowel disease, and rheumatoid arthritis are traditionally managed by regular hospital reviews initiated by a physician. Prebooked reviews may occur when the patient is well and little action is taken.1 The volume of appointments leads to an unwieldy system struggling to respond rapidly to requests for help in the face of fluctuating disease.

General practitioners believe that for such patients rapid specialist access in times of need is more important than routine hospital follow up,2 3 but hospital specialists may be reluctant to relinquish routine reviews.4 A study exploring the use of other professionals for routine reviews in asthma suggested that reviews had simply been moved into primary care,5 while a randomised controlled trial in rheumatoid arthritis showed other professionals could be effective.6

Lengthening periods between reviews or increasing discharge rates7 make some impact but do not address the fundamental belief that lifelong review is necessary and should be medically driven. Patients with chronic disease manage their condition every day and initiate appointments with their general practitioners when they are unwell, therefore hospital reviews initiated by the patient could be considered. This might reduce unnecessary reviews, increase capacity for rapid response to disease flares, and empower patients.8 Randomised controlled trials of such “open access” in inflammatory bowel disease found no clinical detriment but no saving in resources,9 while patients with ulcerative colitis managed their condition more rapidly in a crisis and requested fewer reviews.10

Rheumatoid arthritis is a chronic disease with unpredictable periods of inflammatory activity, culminating in disability, bone erosion, reduced range of movement, and fluctuating pain and psychological distress.11 Patients have lifelong hospital reviews, initiated by rheumatologists every three to six months, which form about three quarters of a rheumatologist’s workload.12 Rheumatoid arthritis is therefore an appropriate disease to test a new system of access to review in chronic illnesses that use considerable NHS resources.13 14 A two year randomised controlled trial of the two types of review (initiated by patient or by rheumatologist) found that direct access was safe, cost effective, and appreciated,15 and findings were maintained at four years.16 To date, only short term effects of alternative access systems have been studied, but patients with chronic disease who do not have routine reviews may have long term physical consequences (they may not notice gradual physical changes that will go untreated) and therefore long term studies are required.

We extended the two year trial17 to six years to see whether such patients show an improvement in clinical and psychological outcome, reduce their overall use of healthcare resources, and have greater satisfaction with care compared with patients receiving traditional review initiated by a rheumatologist.

Two tables of extra data can be found on bmj.com
Methods

We originally invited consecutive patients who had had rheumatoid arthritis for more than two years and who were attending for routine outpatient reviews to participate in a two year randomised controlled trial, irrespective of clinical status. Randomisation was performed blind, using computer generated numbers concealed in envelopes prepared by an independent party. If patients agreed to participate we then sought consent from their general practitioners. Patients who took part in the two year study were afterwards invited to continue the study for a further four years.

Access to care

Patients in the group in which review was initiated by the patient (direct access) were not offered routine hospital reviews, and their general practitioners were given a short leaflet to support day to day management of patients. Patients (or general practitioners) arranged reviews with a rheumatologist, physiotherapist, or occupational therapist through a nurse-led telephone helpline. Fortnightly direct access clinics gave a maximum delay of 10 working days before appointments, though patients could receive immediate advice from a nurse.

Patients in the control group continued with traditional hospital reviews ordered by the rheumatologist every three to six months according to normal practice, and, as usual, requests for urgent reviews were made by general practitioners through the secretary and accommodated as quickly as possible. At each appointment patients in both groups were managed according to clinical need.

Outcome measures

Clinical status—Each year we assessed pain and the patients’ opinion of disease activity (10 cm visual analogue scales), early morning stiffness, and disability (health assessment questionnaire22) by postal questionnaires. At four, five, and six years we added a generic quality of life measure (SF-36).23 Every two years (baseline and two, four, and six years) we assessed plasma viscosity, C reactive protein, haemoglobin concentration, grip strength, range of movement (elbows and knees), and bony erosions (hand x ray films). Case notes were independently reviewed at two years (covering baseline to two years) and six years (covering four to six years) to assess complications of rheumatoid arthritis.

Psychological status—We also carried out annual postal assessments of anxiety and depression (hospital anxiety and depression scale),24 helplessness (arthritis helplessness index subscale),25 self efficacy (arthritis self efficacy scales),26 and satisfaction with and confidence in the system (10 cm visual analogue scales).

Appointment use—We recorded all visits to hospital rheumatologists and visits to general practitioners for problems related to arthritis. During the two year study there was no difference between the groups in visits to occupational therapy and to physiotherapy27 so we did not measure these in the extension period.

Statistical analysis

The original two year randomised controlled trial was designed to show a difference of 12% in pain at 95% power (n = 186),28 and 182 datasets were completed.29 The extension to six years gave 120 completed datasets, which reduced the power to 81%. As most outcome measures had skewed distributions, we used medians, interquartile ranges (first and third), and non-parametric tests. We summarised differences between the two groups over time using both the median change from baseline to six years and the area under the curve for repeated observations at baseline and at two, four, and six years (trapezoidal rule) and tested them with the Mann-Whitney U test (applying the Kruskal-Wallis test first when we compared multiple groups) with a two tailed significance at the 5% level. Seventy four patients had x ray films at baseline and six years (39 direct access, 35 controls) assessed by the Larsen index (sum of the 14 joint damage scores of each hand, plus two wrist scores weighted by 5).23 24 We used the Townsend deprivation score as a measure of socioeconomic status.25

Results

Of 302 patients invited to participate, 209 agreed. Patients who declined were significantly older than those who participated (median 69 years v 58 years, P<0.05) and more disabled (median score on health assessment questionnaire 2.2 v 1.5, P<0.05). At six years 120 patients remained for analysis (68 (65%) in direct access group and 52 (50%) in control group, P=0.04) (fig 1). Thirty patients died (12 in the direct access group and 18 in the control group). Using the last observation, we found no significant difference or strong directional trend for clinical or psychological outcomes between the groups for those who died. Because those who died were significantly older at baseline (median difference 10 years) and many outcomes were related to age, we excluded these patients from further comparison. The 59 surviving patients who did not complete the study (direct access 25, control 34) were similar at baseline to those who completed the study, differing only for longer duration of disease and less range of movement (table 1).

The 120 patients (direct access 68, control 52) who formed the final dataset differed at baseline only for stronger grip strength in the direct access group (table 1). The Townsend deprivation score25 was not significantly different between groups.
Discussion

Patients using direct access for hospital review of their rheumatoid arthritis fare as well clinically and psychologically over six years as patients receiving traditional review initiated by a rheu-

Table 1  Baseline characteristics (excluding deaths). Figures are medians (interquartile range) unless stated otherwise

<table>
<thead>
<tr>
<th></th>
<th>Did not complete study (n=59)</th>
<th>Direct access group</th>
<th>Completed study (n=120)</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>59</td>
<td>68</td>
<td>52</td>
<td>50</td>
</tr>
<tr>
<td><strong>Median (IQ range)</strong></td>
<td>55 (46.0 to 66.0)</td>
<td>58.0 (48.3 to 65.0)</td>
<td>57.0 (48.3 to 66.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Disease duration (years)</strong></td>
<td>43</td>
<td>65</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td><strong>% female</strong></td>
<td>59</td>
<td>68</td>
<td>52</td>
<td>50</td>
</tr>
<tr>
<td><strong>CRP (mg/l)</strong></td>
<td>48</td>
<td>2.60 (1.50 to 4.90)</td>
<td>3.00 (1.73 to 5.58)</td>
<td>3.10 (1.42 to 4.80)</td>
</tr>
<tr>
<td><strong>PV (mPa)</strong></td>
<td>48</td>
<td>22.5 (4.30 to 60.0)</td>
<td>30.0 (10.0 to 60.0)</td>
<td>30.0 (10.0 to 60.0)</td>
</tr>
<tr>
<td><strong>PV (mPa)</strong></td>
<td>52</td>
<td>15.0 (10.0 to 26.8)</td>
<td>11.5 (10.0 to 22.8)</td>
<td>10.0 (10.0 to 19.5)</td>
</tr>
<tr>
<td><strong>CRP (mg/l)</strong></td>
<td>52</td>
<td>1.74 (1.67 to 1.76)</td>
<td>1.73 (1.67 to 1.76)</td>
<td>1.73 (1.67 to 1.79)</td>
</tr>
<tr>
<td><strong>CRP (mg/l)</strong></td>
<td>53</td>
<td>124 (115 to 133)</td>
<td>125 (125 to 138)</td>
<td>125 (118 to 131)</td>
</tr>
<tr>
<td><strong>Disability (HAQ)</strong></td>
<td>47</td>
<td>1.50 (0.0 to 2.25)</td>
<td>1.25 (0.625 to 1.875)</td>
<td>1.375 (0.625 to 1.875)</td>
</tr>
<tr>
<td><strong>Grip strength (kg)</strong></td>
<td>47</td>
<td>10.0 (8.0 to 18.0)</td>
<td>10.0 (8.0 to 18.0)</td>
<td>10.0 (8.0 to 20.0)</td>
</tr>
<tr>
<td><strong>CRP (mg/l)</strong></td>
<td>52</td>
<td>18.0 (14.0 to 21.0)</td>
<td>16.5 (14.0 to 19.3)</td>
<td>16.0 (12.0 to 19.0)</td>
</tr>
<tr>
<td><strong>Depression (0-20)</strong></td>
<td>47</td>
<td>5.0 (2.5 to 7.0)</td>
<td>5.0 (2.5 to 7.0)</td>
<td>5.0 (2.5 to 7.0)</td>
</tr>
<tr>
<td><strong>Self efficacy (10-100)</strong></td>
<td>47</td>
<td>62.0 (44.0 to 76.0)</td>
<td>62.0 (44.0 to 76.0)</td>
<td>62.0 (44.0 to 76.0)</td>
</tr>
<tr>
<td><strong>Function</strong></td>
<td>46</td>
<td>62.0 (35.0 to 83.0)</td>
<td>67.3 (45.0 to 86.7)</td>
<td>60.2 (44.1 to 81.4)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>47</td>
<td>68.0 (47.0 to 82.0)</td>
<td>70.0 (53.3 to 80.0)</td>
<td>70.0 (50.9 to 80.0)</td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td>46</td>
<td>8.8 (7.2 to 9.7)</td>
<td>8.8 (7.3 to 9.7)</td>
<td>8.8 (7.6 to 9.6)</td>
</tr>
<tr>
<td><strong>Confidence</strong></td>
<td>47</td>
<td>9.3 (8.4 to 9.6)</td>
<td>9.3 (8.6 to 9.6)</td>
<td>9.3 (8.6 to 9.5)</td>
</tr>
</tbody>
</table>

CRP=C reactive protein, PV=plasma viscosity, HAQ=health assessment questionnaire.

**P value**
- **<0.005:** confidence: 8.4 (7.25-9.45) v 8.0 (5.72-8.7), P = 0.04
- **<0.0001:** with 34% of direct access patients receiving more than 10 hospital reviews during years four to six. This includes three patients who did not request any appointments over the six years. During years four to six we recorded the intervals between patients' requests and subsequent appointments. These were not different between groups (direct access requested 166 appointments, median delay 6 days, 5-9; controls requested 10 additional appointments, median 8 days, 4.5-11.25). The number of visits to the general practitioner was not significantly different between the groups over the six years (median 8, 5-20; v 9.5, 5-17).

**Discussion**

Patients using direct access for hospital review of their rheumatoid arthritis fare as well clinically and psychologically over six years as patients receiving traditional review initiated by a rheu-
matologist, but use fewer appointments and are more satisfied with and confident in their system of care.

Limitations
The 93 patients who declined to participate were older and had greater disability, possibly suggesting that such patients may be less amenable to change (data not collected). After randomisation more control than direct access patients withdrew, and repeated questionnaires and research visits in the absence of perceived benefit may have been a disincentive to those in the control group. Patients who withdrew had had rheumatoid arthritis for longer and less range of movement at baseline, but outcome data available at two years showed no major differences compared with those who completed the study (data not shown). Changes in clinical and psychological outcomes in those using direct access were no different over six years to changes in patients using traditional reviews initiated by a rheumatologist. Range of movement in the elbow deteriorated less in the direct access group but goniometry measurements can be imprecise.

Table 2 Median changes in outcome from baseline to six years

<table>
<thead>
<tr>
<th>Measurement*</th>
<th>Direct access group</th>
<th>Control group</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical measures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain (0-10)†</td>
<td>1.25 (-0.40 to 3.25)</td>
<td>1.1 (-1.0 to 3.60)</td>
<td>0.91</td>
</tr>
<tr>
<td>Disease activity (0-10)†</td>
<td>0.25 (-1.35 to 2.80)</td>
<td>0.25 (-0.88 to 2.80)</td>
<td>0.49</td>
</tr>
<tr>
<td>Early morning stiffness (0-1440 mins)†</td>
<td>0 (-10.0 to 33.0)</td>
<td>5.0 (-15.0 to 20.0)</td>
<td>0.80</td>
</tr>
<tr>
<td>CRP (&lt;10-200 mg/l)†</td>
<td>-0.95 (-12.0 to 20.5)</td>
<td>-3.00 (-8.4 to 3.0)</td>
<td>0.62</td>
</tr>
<tr>
<td>PV (1.5-2.7 mPa)‡</td>
<td>0.07 (-0.01 to 0.14)</td>
<td>0.07 (-0.04 to 0.16)</td>
<td>0.78</td>
</tr>
<tr>
<td>Haemoglobin (50-170 g/l)‡</td>
<td>-0.95 (-12.0 to 20.5)</td>
<td>-3.00 (-8.4 to 3.0)</td>
<td>0.62</td>
</tr>
<tr>
<td>PV (1.5-2.7 mPa)‡</td>
<td>0.07 (-0.01 to 0.14)</td>
<td>0.07 (-0.04 to 0.16)</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Disability (HAQ) (0-3)†</strong></td>
<td>0.19 (-0.125 to 0.75)</td>
<td>0.25 (0 to 0.75)</td>
<td>0.39</td>
</tr>
<tr>
<td><strong>Grip strength (0-72 kg)‡</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right hand</td>
<td>-4.0 (-10.0 to 0)</td>
<td>-2.0 (-5.5 to 2.0)</td>
<td>0.13</td>
</tr>
<tr>
<td>Left hand</td>
<td>-4.0 (-10.0 to 0)</td>
<td>-1.0 (-7.0 to 0)</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>Range of movement (elbow 0-150°, knee 0-140°)‡</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right elbow</td>
<td>-17.0 (-35.0 to 0)</td>
<td>-25.5 (-40.5 to -14.5)</td>
<td>0.04</td>
</tr>
<tr>
<td>Left elbow</td>
<td>-15.0 (-25.0 to 0)</td>
<td>-24.5 (-40.3 to -4.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Right knee</td>
<td>-4.0 (-20.0 to 7.0)</td>
<td>-8.0 (-30.0 to 7.0)</td>
<td>0.66</td>
</tr>
<tr>
<td>Left knee</td>
<td>-5.0 (-20.0 to 5.0)</td>
<td>-8.5 (-28.3 to -4.5)</td>
<td>0.65</td>
</tr>
<tr>
<td><strong>Larsen index, both hands (0-190)†</strong></td>
<td>14 (0 to 27)</td>
<td>9 (2 to 23)</td>
<td>0.69</td>
</tr>
<tr>
<td><strong>Psychological measures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pain (0-21)†</strong></td>
<td>0 (-2.0 to 3.0)</td>
<td>0 (-2.0 to 3.0)</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Depression (0-21)†</strong></td>
<td>0 (-1.0 to 3.0)</td>
<td>0 (-1.0 to 2.75)</td>
<td>0.80</td>
</tr>
<tr>
<td><strong>Helplessness (0-30)‡</strong></td>
<td>0.5 (-3.0 to 3.0)</td>
<td>1.0 (1.75 to 4.0)</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Self efficacy (0-100)‡</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td>2.0 (-12.0 to 16.0)</td>
<td>1.0 (-10.0 to 19.0)</td>
<td>0.49</td>
</tr>
<tr>
<td><strong>Function</strong></td>
<td>-2.75 (-15.9 to 5.0)</td>
<td>-8.6 (-20.6 to 2.40)</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>-3.30 (-11.6 to 8.3)</td>
<td>-6.7 (-15.0 to 6.7)</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>Satisfaction (0-10)‡</strong></td>
<td>0.5 (-0.7 to 0.9)</td>
<td>-1.1 (-2.70 to 0.25)</td>
<td>0.0004</td>
</tr>
<tr>
<td><strong>Confidence (0-10)‡</strong></td>
<td>-0.15 (-0.73 to 0.43)</td>
<td>-1.0 (-2.35 to 0.20)</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

* Mann Whitney U test.
† Lower scores indicate better health.
‡ Higher scores indicate better health.
§ Significant difference between two groups at 5% level.

**Fig 2** Patients’ confidence and satisfaction in the system

**Fig 3** Hospital rheumatologist appointments over six years
The complication rate was not significantly different between groups, but the number of complications and need for surgery seemed to increase in both groups during the latter part of the study, perhaps because by then patients had had the disease for longer or because different assessors had to be used at the two time points. Patients’ satisfaction and confidence were high for both systems but diminished in patients in the control group over the six years.

Direct access patients had 38% fewer appointments with a rheumatologist than patients in the control group. Some direct access patients requested few or even no appointments, and the research visits at two, four, and six years may have acted as a safety net for them. In the clinical direct access service established in our trust after this trial, patients who have not requested an appointment in the previous two years are reviewed by a nurse specialist. After excluding pure research visits from our data, we calculate that an average of 11% of direct access patients each year will not request a review. Some costs are needed to set the service up (organising education of patients, helpline, nurse reviews, general practitioner guidelines, appointment systems), but in the longer term, resources released by fewer appointments with a rheumatologist should offset this initial investment.

The power of the study inevitably declined over six years, but overall, out of 22 outcomes, 12 were more favourable for direct access patients (four significantly) compared with only six favouring control patients (none significantly). It is possible that with a larger population of patients completing to six years, some of these borderline differences might have reached significance, and those seen at two years (pain and self efficacy) might have been maintained.

Blinding of patients, the physician, and assessors to group allocation was not possible, giving the potential for bias. The study patients, however, formed a minority of the physician’s caseload, and it is unlikely that a systematically different approach to these 120 patients was maintained for six years, while the use of a single physician minimised the confounding variable of differing clinical management. Patients and assessors completed validated standardised outcome measures and would be unlikely to be able to maintain a consistent bias.

Differences to other studies
This study differs importantly from others in that it uses direct access to replace rather than complement routine review and the key point of access is clinical, not administrative. It shows potential resource savings rather than transferring resources to primary care, and the results can be maintained without clinical detriment in the long term. Forthcoming analyses will add important questions, including the timing and efficacy of appointments by using additional clinical data collected during years four to six, and assessing missed clinical need by analysing a combined review from the occupational therapist and physiotherapist of a random sample of patients at six years.

This trial used consecutive patients with rheumatoid arthritis and should therefore be generalisable, but local issues (patients, staff, administrative) may influence systems and outcomes, therefore a multi-centre study with various hospital settings is needed to ascertain the generalisability of direct access. Other research could explore the altered roles of general practitioners, hospital physicians, patients, and nurses in management of chronic disease.

Conclusions
The traditional system of routine hospital follow up in chronic disease is a drain on NHS resources and a burden for patients if they are well. Direct access initiated by patients challenges the traditional view that medically driven regular hospital review is required and reduces the volume of perhaps unnecessary reviews, while targeting them to support clinical need and reflect the NHS commitment to the “expert patient.” If this system was instigated on a large scale, the resources released could be used to improve care in other ways (for example, by reducing waiting times for new patients) or to increase the overall throughput of outpatients (by supporting up to a third more patients). Furthermore, this model could be tested in other chronic inflammatory illnesses that encompass a degree of self management, such as asthma, diabetes, and inflammatory bowel disease.

We thank Susan Tipler (nurse specialist managing the helpline), Julie Haynes (research sister, years one and two), Wendy Harrison (clinical coordinator), and Sarah Browning (project secretary). We are grateful to Gina Ludlum (occupational therapist), Petra Allerston (physiotherapist), Shelagh Snow, and Vanessa Lock (research sisters) for reviewing patients and case notes, and to Ben Bennett (trust manager) for administrative advice. In particular we thank the patients, without whom the study could not have taken place.

Contributors: SH and JK initiated the original study and together with JP and DM initiated the extension. The trial steering group comprised SH, JK, JP, DM, KM, and MH. SH supervised the study management, KM and MH collected the data, MGP reviewed data, and PSB and SH analysed the data. All authors participated in discussing the results and in writing and editing successive drafts of the paper. SH and JK are guarantors.

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Competing interests: None declared.

Ethical approval: Local research ethics committee approval was given for the original two year trial and the subsequent four year extension.


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